Haemonetics®
MCS®+ Device
LN 9000 Operator and Maintenance Manual

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Buyer's Use of Products

Haemonetics Corporation warrants only the Haemonetics MCS®+ device as supplied by it. When properly assembled, maintained and operated by a qualified operator, the MCS+ device has the capacity of safely and adequately performing both collection protocols and therapeutic procedures.

Refer to Chapter 2, *System Description*, for the machine symbol chart.

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNING!

This manual provides certain basic information concerning the maintenance and operation of the Haemonetics MCS+ device and is intended to be used in conjunction with and as a supplement to the training supplied by a Haemonetics Clinical Specialist or other qualified personnel. Departures or deviations from the procedures contained in this manual should not be made except in conformity with official changes made to the manual by Haemonetics Corporation. Other departures or deviations are at the operator's own risk.

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- Secure training in the procedures to be used.
- Apply in vitro studies to verify the ability to use the products safely in vivo.

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Chapter One

INTRODUCTION

OVERVIEW OF THE MCS®+ DEVICE 1-2

OVERVIEW OF THE MCS+ DEVICE

Using the latest computer and blood processing technology, the Haemonetics MCS®+ Device LN 9000 (see Figure 1-1) collects blood components, including platelets, and plasma.

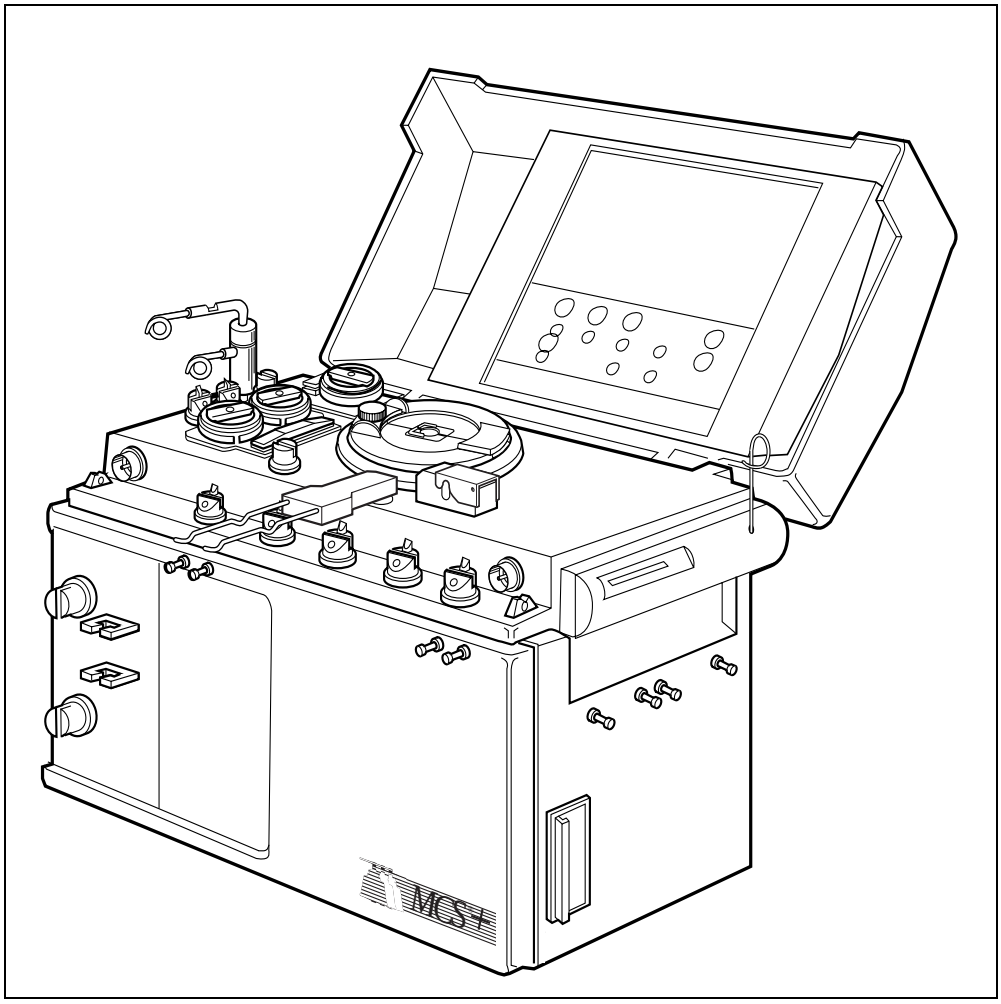

Figure 1-1, The Haemonetics MCS+ Device LN 9000

The MCS+ Device combines advanced technology with portability and ease-of-use. The system is lightweight and compact. A removable program card, called the Protocol Card, makes it possible to upgrade the operating program of your machine without opening the cabinet.

Among the characteristics of the MCS+ device are:

- A third pump, referred to as the White Pump, that enables the MCS+ device to maintain a more consistent “critical flow,” gaining better control of the platelet collection process.

✍ *Note: The White Pump has also been referred to as the Plasma Pump and the Surge Pump.*

- A large, interactive user interface that provides ample feedback and on-line help.
- The “HaemoCalculator” function, which is an integral part of the computer control. The HaemoCalculator allows the operator to input donor or patient information to optimize the blood component collection process.
- The “HaemoUpdate” function, which gives the operator a full running update of all procedure details at any time.
- A removable Protocol Card that makes it possible to change or upgrade the collection protocols performed by the MCS+ device without opening the cabinet and without the help of a service technician.
- A drip monitor that monitors the flow of anticoagulant.
- An identification system that checks the disposable type and ensures that the appropriate protocol is selected.

Chapter Two

SYSTEM DESCRIPTION

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GENERAL SYSTEM DESCRIPTION

The MCS®+ is a lightweight, compact, blood processing instrument. The system consists of two parts: the machine and the single-use blood processing disposable.

On the inside of the MCS+ device cover, there is a Display Screen on which messages regarding the operation of the system are shown. Located directly beneath the Display Screen is a Control Panel through which the operator selects protocols and enters information.

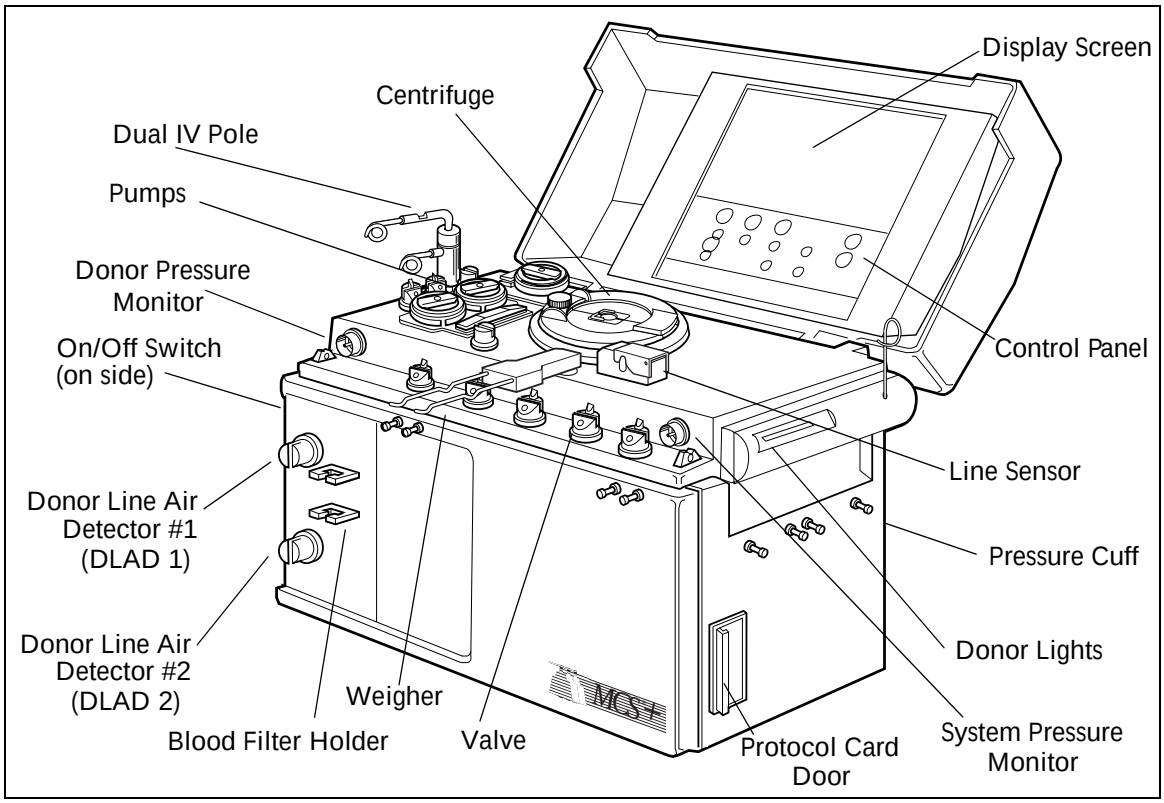


Figure 2-1, System Components

On the front of the MCS+ device cabinet (Figure 2-1)are a Blood Filter Holder and two pressure monitors that check the pressure in the disposable set. On the left side of the cabinet is an anticoagulant drip monitor, which monitors the flow of anticoagulant. On the right side of the cabinet is the Protocol Card door.

In various locations on the cabinet are four air detectors that check for the presence of fluid or air in the tubing.

On the MCS+ device deck (Figure 2-2) are a Centrifuge in which the processing chamber is placed and three rotary pumps that move fluids through the system.

In various locations on the deck are seven valves that control the fluid pathway. A Line Sensor monitors the density of fluid in the effluent line of the bowl.

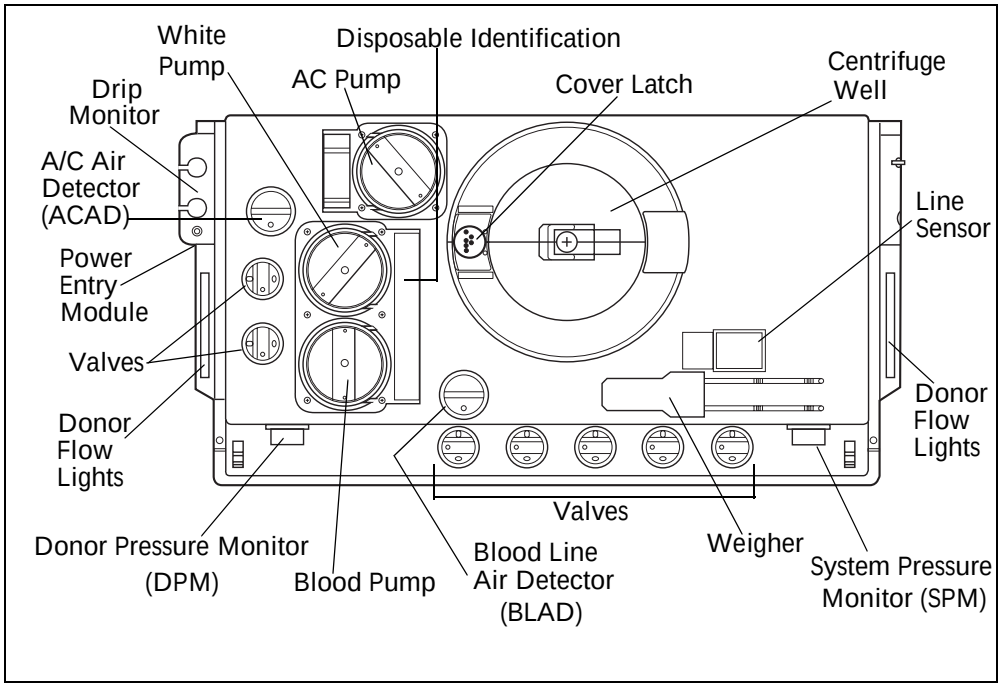


Figure 2-2, Top View of Deck

Several disposables are available. Each is designed to provide optimal results when collecting the specific component required.

All disposables include the following:

a. Tubing harness through which blood flows

b. Centrifuge bowl in which blood is separated into its components

c. Collection bag(s) into which component(s) are collected

POWER ENTRY MODULE

The Power Entry Module, located on the left side of the machine, performs three functions.

a. ON/OFF. The first function is to power the machine on and off. In case of an emergency, this button stops all machine function.

b. FUSE PANEL. The second function is to act as a fuse panel to interrupt power to the machine in the event of excessive current draw.

c. INPUT POWER RECEPTACLE. This machine component allows the connection to the power cord.

USER PANEL

The MCS+ device is operated through the User Panel; the system provides information regarding the status of procedures through Donor Flow Lights and through the Display Screen. All keys are covered by a washable plastic cover to protect them from spills.

The MCS+ device User Panel (Figure 2-3) consists of three main sections: the Donor Flow Lights, the Display Screen, and the Control Panel.

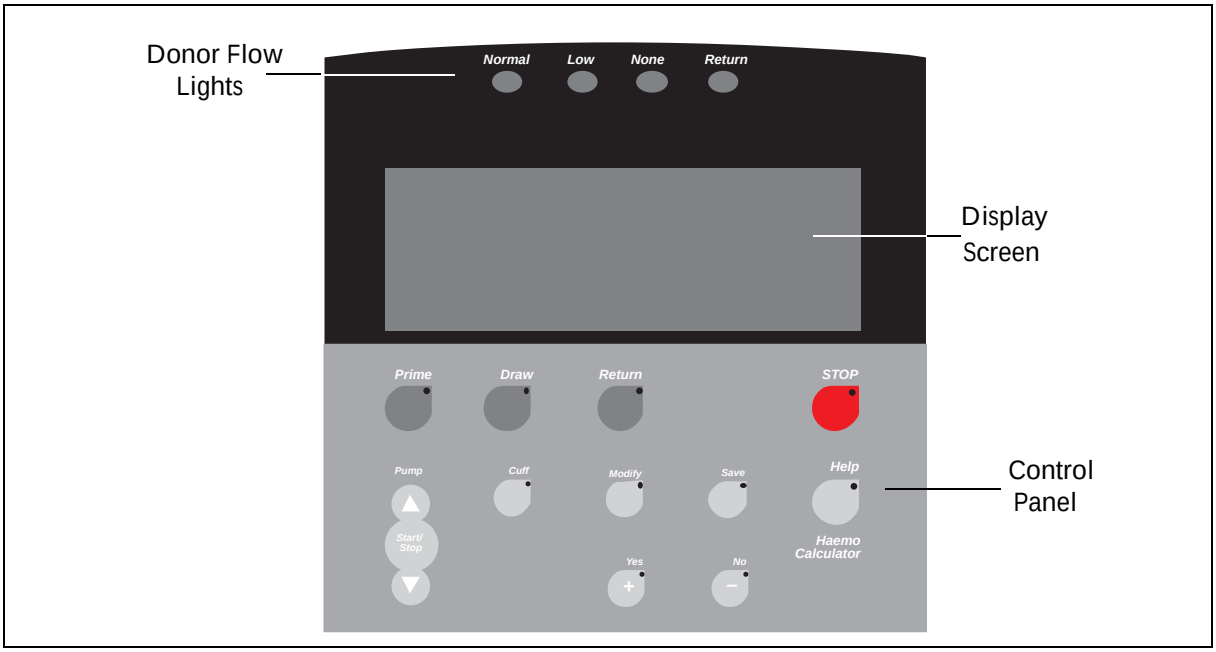


Figure 2-3, MCS+ Device User Panel

DONOR/PATIENT FLOW INDICATORS

Donor Flow Lights

During Draw, the Donor Flow Lights (Figure 2-4), located on both sides of the deck and on the cover, indicate the status of the flow to and from the donor/patient. If the programmed pump speed is not compatible with the flow, adjust the Blood Pump speed using the pump keys located on the control panel to meet the individual donor/patient requirement.

During Draw, one of the Donor Flow Lights is illuminated.

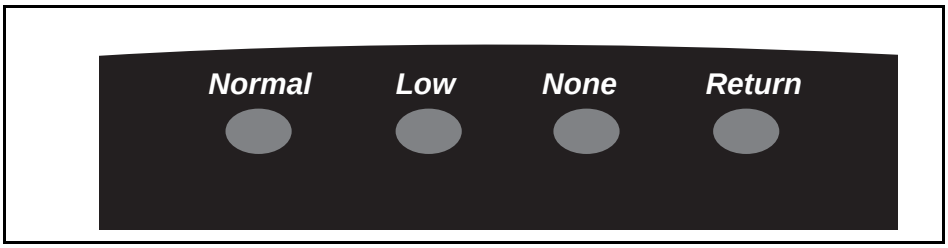


Figure 2-4, Donor Flow Lights

The four sets of Donor Flow Lights are located at the top of the panel, the sides of the cabinet, and the outside of the cover.

These lights indicate status of the flow: Normal (green), Low (yellow), None (red), or Return (yellow).

NORMAL FLOW

The green lights are illuminated to indicate that the Blood Pump is able to maintain a speed greater than 2/3 of the programmed speed. The Blood Pump's speed decreases by 5 ml/min each second if the donor/patient pressure falls below -50 mmHg. Once the donor/patient pressure increases again, the pump speed increases at a rate of 5 ml/min each second. This pressure is measured and communicated to the MCS+ device computer by the Donor Pressure Monitor (DPM).

LOW FLOW

The yellow Donor Flow Lights are illuminated to indicate that the donor/patient flow rate is below 2/3 of programmed speed.

NONE

The red light is illuminated to indicate that there is no flow. When the flow stops, the Blood Pump and AC Pump automatically stop. The Centrifuge continues to spin to maintain separation. The Blood and AC Pumps automatically restart when the donor/patient blood flow is restored. The White Pump remains active.

RETURN

During Return, the only donor/patient flow indicator lights that illuminate are yellow in color and are at the outermost end of the indicator panels.

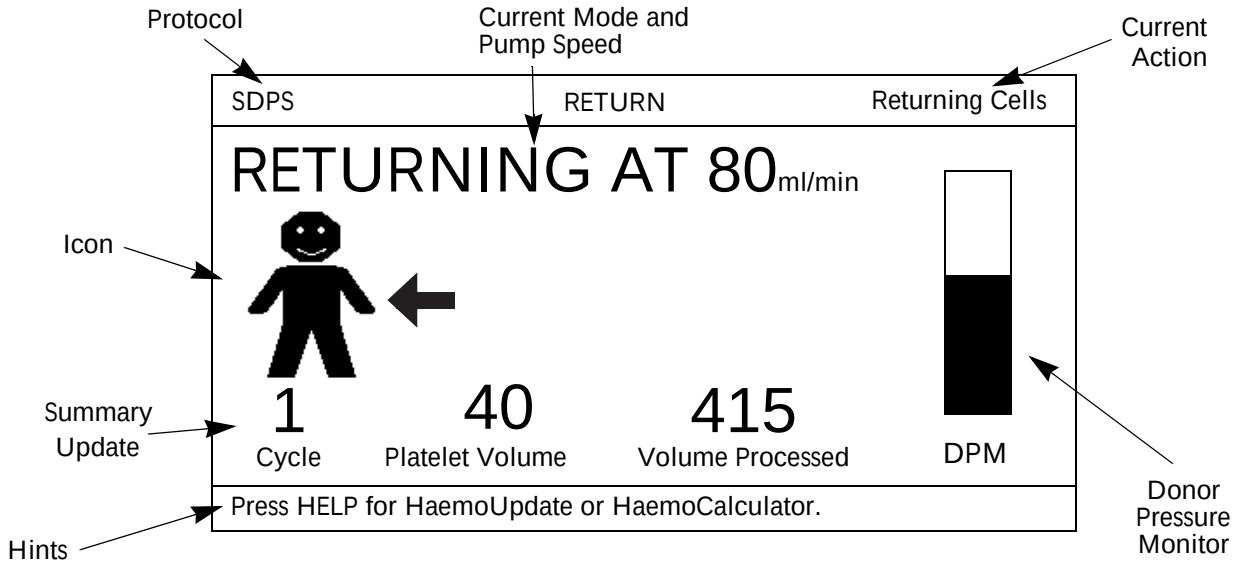
These yellow lights indicate to the donor/patient and to the operator that the remaining components are being returned to the donor/patient.

SCREENS

Screens in this section are shown for layout only. The displays shown on your MCS+ device may vary depending upon the protocol selected. Refer to the applicable protocol section for actual screen contents.

Main Screen

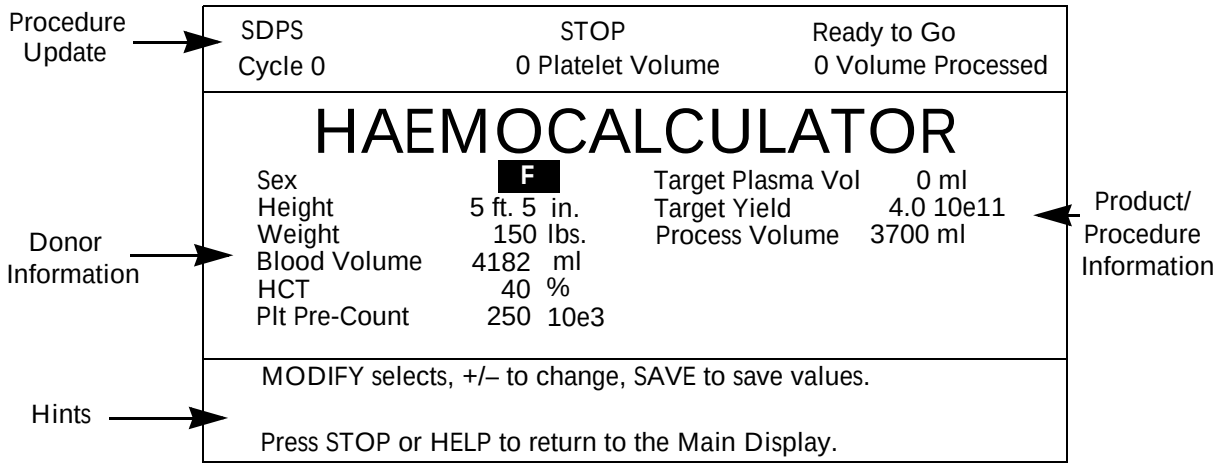
The Display Screen provides frequent updates on the status of the particular procedure in use. The following illustration shows a screen that might be seen during the Return mode of the Single Donor Platelets protocol.



All data on the display is continually updated. The level of the dark area on the DPM image rises and falls with the pressure sensed at the Donor Pressure Monitor. Pressing HELP/HAEMOCALCULATOR any time during processing will display the HaemoUpdate screen. Pressing HELP/HAEMOCALCULATOR a second time causes the HaemoCalculator screen to be displayed.

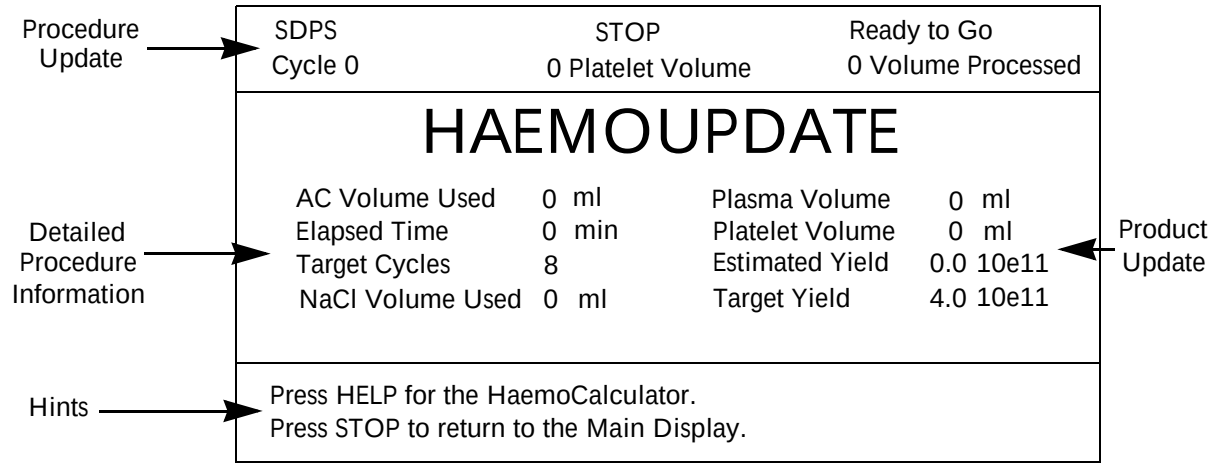
Haemo-Calculator

From a Main Screen display, pressing HELP/HAEMOCALCULATOR once displays the HaemoUpdate screen. Pressing HELP/HAEMOCALCULATOR a second time displays the HaemoCalculator screen, shown below.



HaemoUpdate

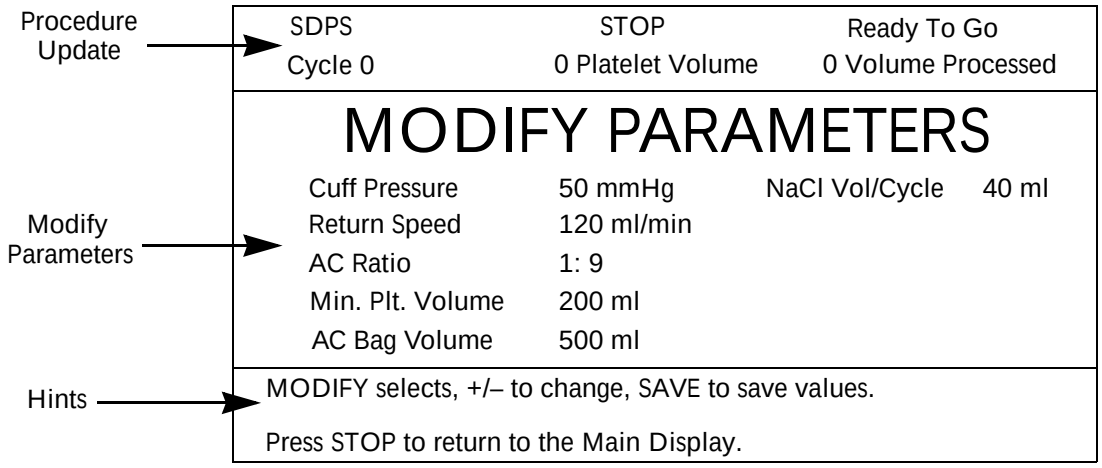
During normal operation, with no warnings displayed, pressing HELP/HAEMOCALCULATOR once causes a HaemoUpdate screen to be displayed. A sample HaemoUpdate display is shown below.



Modify

Using the MODIFY key, it is possible to change a protocol parameter before or at any time during a procedure without interrupting the procedure.

To view or change the default parameters, press the MODIFY key. To select a parameter value, scroll through the list using the MODIFY key. Change a value using the + (YES) and – (NO) keys.



To permanently save the modified value(s), press the SAVE key. These values will replace the default values. If you want to modify a value for only one procedure, do not press SAVE. If your changes are not saved, they will be in effect only until the system is powered off or the current procedure ends, at which time the system reverts to the default parameters. Repeat this process each time you wish to modify the parameters.

✍ *Note: Pressing the mode control key (DRAW, RETURN, or STOP) for the current mode returns you to the main screen in the current mode without interrupting the procedure.*

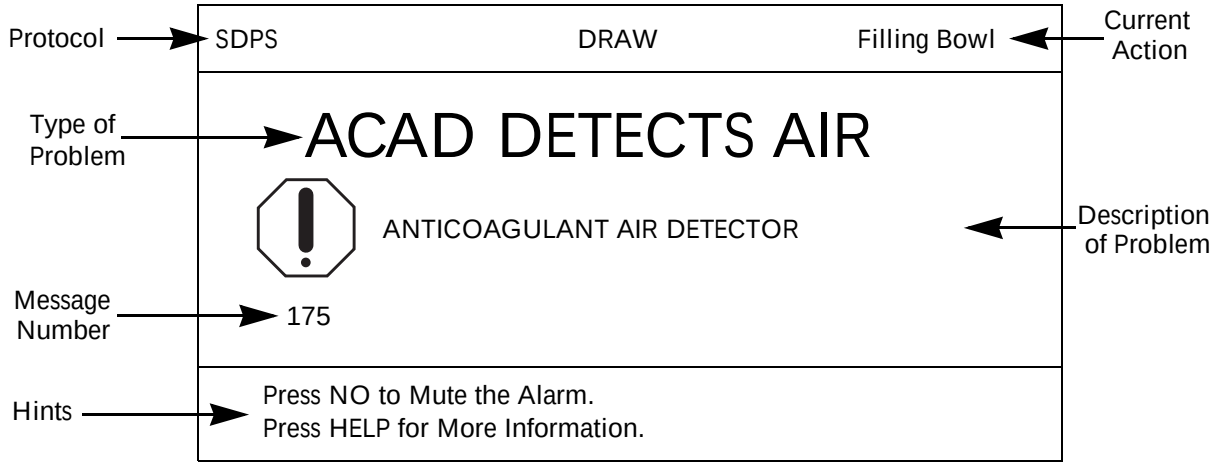
Operator Configuration

Operator Configuration is available only in Platelet Protocol Software Version E or later. Refer to the Platelet Protocol Manual, Part Number 51052-00 for details.

Notice

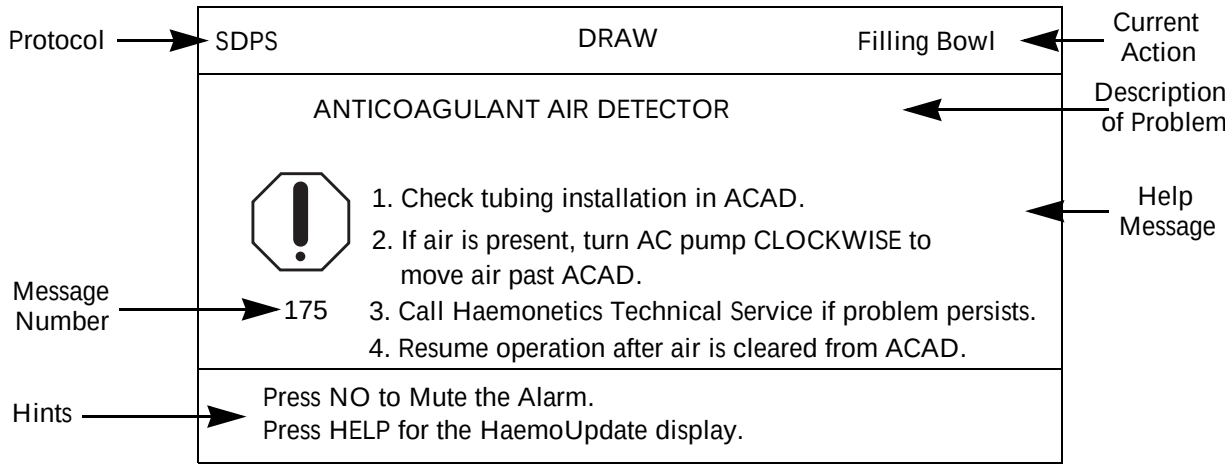
If the MCS+ device encounters an error, the machine stops its pumps, sounds an alarm and displays the Notice screen. The audible alarm can be turned off for up to one minute by pressing NO. Pressing HELP/HAEMOCALCULATOR displays the Help screen, which contains basic guidelines to help solve the problem. Table 5-1 contains a full listing of all messages displayed by the MCS+ device.

✍ *Note: Platelet protocols in Platelet Protocol Software Version E or later have revised notice messages and associated message numbers. Refer to Appendix C of the Platelet Protocol Manual, Part Number 51052-00 for details.*



Help

Each notice message has its own Help message. Help contains the most likely sources of the error and the actions to be taken to solve the problem and continue the procedure. Table 5-1 on pages 5-8 through 5-24 contains a full listing of all messages displayed by the MCS+ device.


Protocol
SDPS
DRAW
Filling Bowl
Current Action
ANTICOAGULANT AIR DETECTOR
Description of Problem
1. Check tubing installation in ACAD.
2. If air is present, turn AC pump CLOCKWISE to move air past ACAD.
Help Message
Message Number
175
3. Call Haemonetics Technical Service if problem persists.
4. Resume operation after air is cleared from ACAD.
Hints
Press NO to Mute the Alarm.
Press HELP for the HaemoUpdate display.

CONTROL PANEL

The operator communicates with the MCS+ device computer through the Control Panel. Each time an active key is pressed, a short beep is sounded.

All system controls are functionally grouped as shown (Figure 2-5).

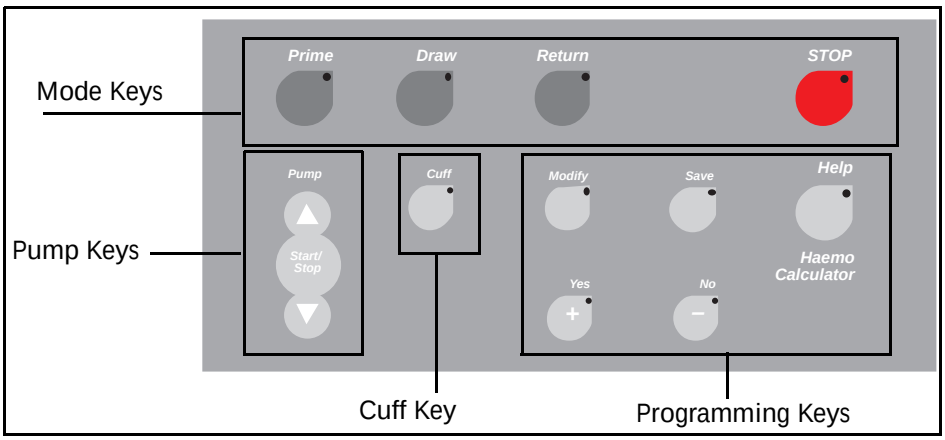


Figure 2-5, Control Panel Keys

KEYS

Mode Keys

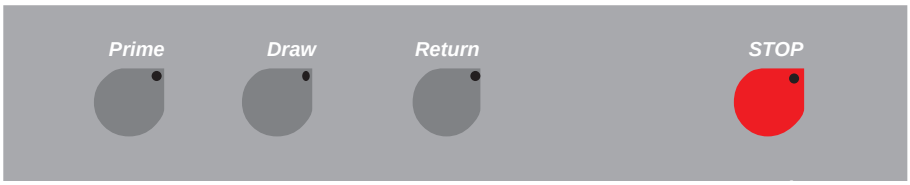


Figure 2-6, Mode Keys

PRIME

When PRIME is pressed, the disposable set is primed with anticoagulant from the anticoagulant spike to the Donor Line Air Detector 1 (DLAD 1).

DRAW

When DRAW is pressed, the procedure is initiated. The Pressure Cuff on the donor/patient inflates and the pumps begin to turn, moving anticoagulated whole blood through the tubing. The Centrifuge begins to spin and all applicable sensors and air detectors are activated.

RETURN

In the Return mode, the machine returns the remaining components to the donor/patient. To initiate an earlier Return, press the RETURN key.

Warning! Press RETURN if the donor/patient exhibits signs of discomfort, such as light-headedness, during Draw. If the donor/patient exhibits signs of discomfort, such as light-headedness, and pressing RETURN does not alleviate these symptoms, then the procedure should be discontinued and medical attention should be given to the donor/patient.

STOP

Pressing STOP brings the pumps and the Centrifuge to a halt, closes all applicable valves, and places the machine in the Ready mode. Pressing STOP does not alter any parameters or interfere with volume accounting. However, the bowl contents do lose separation.

Press the STOP key only when the processing must be stopped immediately. When the pumps need to be stopped, but the centrifuge can keep turning, press the PUMP START/STOP Key. To continue processing, press the PUMP START/STOP Key again.

✍ *Note: If the bowl is more than 1/3 full, continuing to draw after losing separation may interfere with platelet collection performance. In this case, one should enter the Return mode to empty the bowl before continuing the procedure.*

Pump Keys

PUMP START/STOP

During the Draw and Return modes, the PUMP START/STOP key stops the Blood and Anticoagulant Pumps if they are turning, and then restarts the pumps after they have been stopped. This key temporarily stops the machine processing. In the platelet protocols, the White Pump may continue to turn to maintain optimal separation.

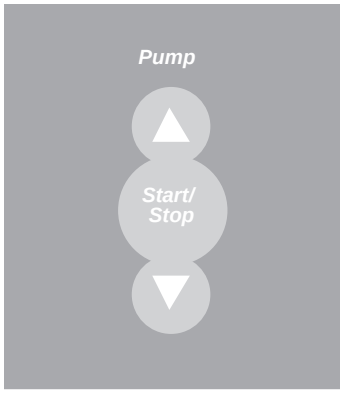


Figure 2-7, Pump Keys

Pressing PUMP STOP/START does not affect Centrifuge operation. Separation of the blood components in the bowl is not affected.

If the Blood Pump is stopped and plasma is available in the plasma bag, the White Pump automatically increases speed to maintain a constant critical flow through the bowl.

✍ *Note: Leaving the MCS+ device in the pump stop mode for extended periods (longer than a few minutes) can cause coagulation in the needle.*

UP/DOWN ARROWS

These keys increase and decrease the pump speed during a procedure.

Pressing the UP/DOWN arrows raises or lowers the Blood Pump speed of the current mode. Any change to the set speed made by using these keys is retained throughout the procedure until another change is made.

✍ *Note: The MCS+ device will automatically adjust the pump speeds in poor flow conditions. A poor flow condition is indicated by the changing level of the bar graph on the display screen and a change in the donor/patient flow indicator lights. Wait until the pump speed is at a constant rate before readjusting pump speed to donor/patient flow.*

Cuff Key

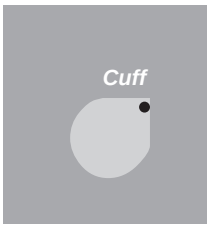


Figure 2-8, Cuff Key

During all procedures, a Tourniquet Cuff placed above the venipuncture site will automatically inflate during the Draw and deflate during Surge and Return. However, the CUFF key can be used during the Draw and Ready modes to release tourniquet pressure. The current status of the Cuff is indicated by the light on the CUFF key. When the light is on, the Cuff is inflated. (Cuff pressure is displayed in Modify screen.)

Programming Keys

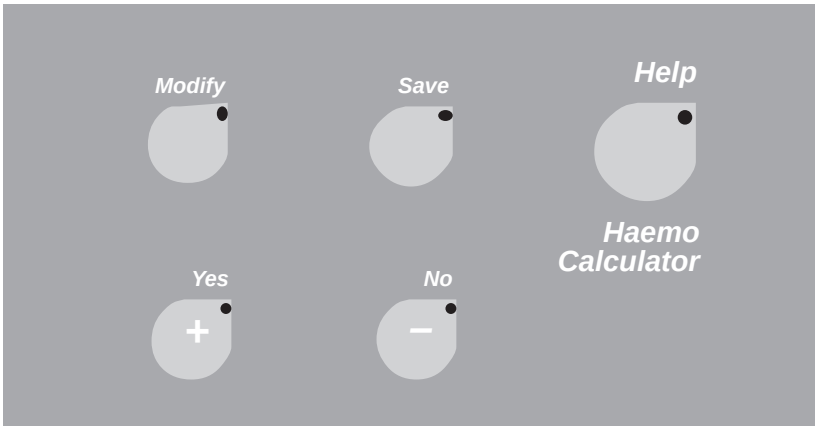


Figure 2-9, Programming Keys

The MCS+ device stores operating parameters. These parameters may be modified through one of the two MCS+ device programming displays. The HaemoCalculator display contains donor/patient and collection parameters and the Modify display contains processing parameters.

MODIFY

When the MCS+ device shows the Main Screen, pressing the MODIFY key displays the Modify Parameters screen. To scroll through parameters, press the MODIFY key when the Modify Parameters or HaemoCalculator screen is displayed.

SAVE

When the Modify Parameters screen is displayed, pressing the SAVE key saves all parameter settings on the screen.

HELP/HAEMOCALCULATOR

The HELP/HAEMOCALCULATOR key is used to obtain additional information. In normal operation, pressing HELP/HAEMOCALCULATOR once results in the display of the full procedure statistics of the HaemoUpdate screen. Pressing HELP/HAEMOCALCULATOR a second time shows the HaemoCalculator display, which contains the donor/patient statistics and procedure collection targets.

YES/+

The YES/+ key is used to confirm a selection or to increase a selected variable in the HaemoCalculator or Modify modes.

NO/-

The NO/- key is used to cancel a selection or to decrease a selected variable in the HaemoCalculator or Modify modes.

PROTOCOL CARD

The Protocol Card contains the operating program for an MCS+ device protocol. The Protocol Card is inserted through a slot inside the Protocol Card door on the right side of the cabinet (Figure 2-10). This arrangement makes it simple to upgrade or change the MCS+ device program(s).

The MCS+ device checks to ensure that a valid card is properly installed before a protocol can be performed. The MCS+ device also checks the disposable set to ensure that the set installed is appropriate for the protocol selected.

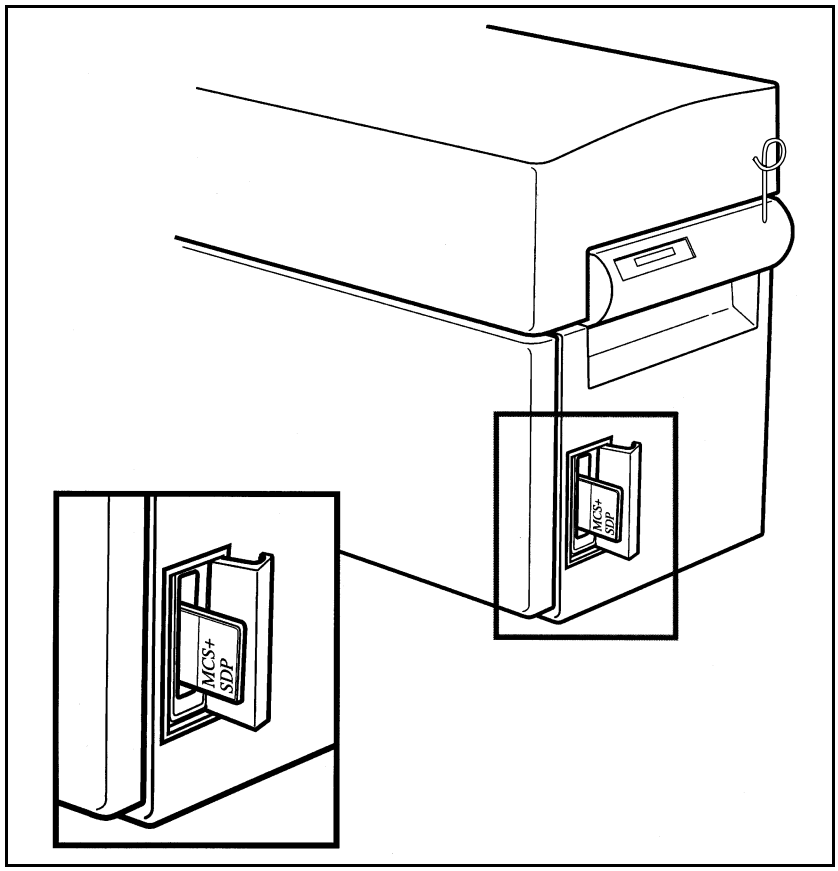


Figure 2-10, Protocol Card Inserted in Protocol Port

To install the Protocol Card, ensure that the MCS+ device is powered off. Open the Protocol Card door and insert the Protocol Card with the label facing toward the front of the MCS+ device (see Figure 2-10). Insert the card fully and then close the card door.

✍ *Note: When the Protocol Card is not installed correctly, the card door will not close.*

Warning! The card door should never be opened during operation of the MCS+ device. Opening the card door may interfere with operation of the MCS+ device.

Protocol Card Pouch

The Protocol Card Pouch provides convenient storage for protocol cards that are not in use. The Protocol Card Pouch may be hung on the two rear bag pins located on the Protocol Card door side of the MCS+ device.

VALVES

There are seven color-coded valves on the MCS+ device deck. The operation of the valves is automatic. Specific valve functions are discussed in the protocol sections.

During power-up, the system performs tests on all of the valves. After a protocol has been selected, the appropriate valves are opened to accept the disposable and their active indicators are illuminated. To open a valve, simply toggle the lever on the top of each valve. It is not normally necessary to open a valve this way unless you wish to reposition a section of tubing.

✍ *Note: Do not interfere with machine operation of any of the valves unless the pumps are stopped or the machine is in the Ready mode. (This occurs if the pumps are temporarily stopped or if the red STOP key on the control panel has been pressed.) Attempting to manually alter the state of any of the valves during normal machine operation causes the system to alarm.*

PRESSURE MONITORS

Donor Pressure Monitor (DPM)

The Donor Pressure Monitor (DPM) is an electronically controlled pressure monitor that regulates the speed of the pumps by providing feedback about the flow to and from the donor/patient.

Pressure is measured in the donor/patient line through a hydrophobic bacteriostatic filter on the disposable set. The DPM monitors pressures as low as -80 mmHg during Draw and as high as +260 mmHg during Return. This information is processed by the computer and displayed via a bar graph on the display screen.

Draw Mode

During Draw, the high end of the bar graph represents a pressure of +50 mmHg, and a low end represents -50 mmHg. The lowest DPM limit during Draw of -80 mmHg is not displayed on the bar graph.

In the presence of insufficient flow from the donor/patient, measured as a negative pressure of -80 mmHg, the DPM stops the pumps, the donor/patient NO FLOW indicator illuminates, and an audible signal alerts the operator to initiate corrective action. The White Pump continues to pump plasma through the bowl to maintain optimal separation during platelet collection.

Warning! Once the DPM is inserted into its port on the MCS+ device it should not be removed, as this component plays an essential role in the monitoring of pressure. If the MCS+ device is switched off or if there is a power failure, do not remove the DPM until the line is clamped. Then, remove the DPM until power has been restored. Once power has been restored, reconnect the DPM and unclamp the line. (The display will tell you when to clamp and disconnect the DPM and when to reconnect and unclamp it.) Any deviation from this procedure may invalidate the ability of the MCS+ device to properly monitor pressure. (Refer to the Recovery Procedure in Chapter 5.)

Return Mode

During Return, the DPM monitors the pressure within the donor/patient line. The bar graph on the display screen indicates a range of pressure from 0 at the bottom to 260 mmHg at the top. If pressure greater than a protocol-determined limit is detected, the Blood Pump slows until there is sufficient change in pressure. At this time, the pump gradually increases speed to the programmed rate. If a pressure in excess of 260 mmHg is detected, the Blood Pump is stopped, a signal sounds, and the message "HIGH RETURN PRESSURE" is displayed.

Any time a high return pressure message is displayed, all control keys are disabled except for the red STOP key. If the Blood Pump alternately stops and restarts and the message high return pressure is displayed, check for and correct any flow obstruction, then lower the Blood Pump speed in order to establish an uninterrupted return flow to the donor/patient.

Warning! A pressure in excess of 260 mmHg indicates a flow obstruction that could cause red blood cell hemolysis or damage to the vein. The following corrective action must be taken: press the PUMP START/STOP key, check for and correct any flow obstruction, relieve the high pressure, and continue the procedure.

System Pressure Monitor (SPM)

The System Pressure Monitor (SPM) ensures that the functionally closed sterile barrier of the rotary seal of the bowl has not been compromised by abnormal pressure.

The SPM alerts the operator if pressure is increasing or decreasing at the bowl seal. The SPM works like the DPM. When the SPM has detected positive pressure in excess of 115 mmHg or negative pressure below -85 mmHg, the pumps stop. Check the tubing on the effluent side of the disposable to determine that there are no obstructions.

If the Centrifuge is spinning and pressure is detected, the Centrifuge continues to spin, but the pumps stop. If the Centrifuge had been stopped, as in a Return mode, only the pumps stop.

WEIGHER

The Weigher measures, in grams, the weight of the fluid in the bag placed on it. For the display, the weight is converted to milliliters using 1.026 grams/milliliter as the conversion factor. The Weigher automatically compensates for the weight of the bag when DRAW is first pressed in the collection protocols.

✍ *Note: For optimal accuracy of the weigher, always be sure to have the weigher arm fully extended. The bag(s) on the weigher arm should hang freely.*

AIR DETECTORS

Anticoagulant Line Air Detector (ACAD)

As the anticoagulant is drawn from the anticoagulant bag to the needle site, it first passes through the drip monitor, the Anticoagulant Pump and then through the Anticoagulant Line Air Detector (ACAD). The ACAD monitors the anticoagulant line to ensure there are no obstructions to the anticoagulant flow and that there is always sufficient anticoagulant in the line.

Blood Line Air Detector (BLAD)

The Blood Line Air Detector (BLAD) is located to the right of the Blood Pump and, although active, is monitoring for air only during Return and at the beginning of Draw.

The BLAD detects the presence of air in the blood line from the bowl to the donor/patient valve during Return and initiates volume accounting during Draw.

During Draw, the presence of fluid in the blood line within the BLAD allows the machine to account for blood pumped. This volume is displayed as “Volume Processed” on the display screen during Draw and Return.

Donor Line Air Detector 1 (DLAD 1)

The Donor Line Air Detector 1 (DLAD 1) monitors the donor/patient line. Detection of fluid by the DLAD 1 during Prime alerts the MCS+ device that priming is complete.

The DLAD 1 also alerts the operator to any air introduced into the system during the Draw mode. Anticoagulated whole blood flows through the DLAD 1. If air is detected, the pumps are stopped, an audible signal is heard, and the display screen alerts the operator with a message.

During Return, this component serves to detect air in the unlikely event that air passes by the BLAD and the Donor Line Air Detector 2 (DLAD 2). If air is detected, the DLAD 1 stops the pumps, sounds an audible alarm, and displays a message.

The DLAD 1 is monitored by the MCS+ device safety system. This provides an extra level of safety in the unlikely event of a malfunction.

Warning! Any time an air detection alarm is heard, immediately attend to the machine and take appropriate action.

Warning! An air detection by the DLAD 1 during Return may indicate a failure of the BLAD and/or DLAD 2. Carefully note the source of air detected. Remove the air from the line, following the procedures given in Chapter 5, *Notice Messages and Troubleshooting*.

Donor Line Air Detector 2 (DLAD 2)

The DLAD 2 is located on the front panel of the MCS+ device below the DLAD 1. This air detector serves as a backup to the BLAD. If, for any reason, air is not detected by the BLAD and the filter chamber is emptied, the DLAD 2 stops the pumps, closes the donor/patient valve, and causes a notice message to display and an alarm to sound.

As an extra measure of precaution, this detector is also monitored by the safety system, which directly stops the pumps upon air detection.

Warning! An air detection by the DLAD 2 during Return may indicate a failure of the BLAD. The operator must carefully note the source of air detected. Remove the air from the line, following the procedures given in Chapter 5, *Notice Messages and Troubleshooting.*

PUMPS

Blood Pump

During anticoagulant prime, the Blood and Anticoagulant Pumps turn simultaneously to prime the inlet side of the donor/patient harness with anticoagulant.

In Draw, the Blood Pump pulls anticoagulated whole blood through the filter chamber of the disposable set and pumps it into the bowl located within the Centrifuge.

During Return, the Blood Pump returns any remaining components from the bowl and plasma bag back to the donor/patient.

✍ *Note: Actual Draw and Return modes for each procedure are defined within each protocol section.*

White Pump

The White Pump pulls plasma from the plasma bag of the disposable set and pumps it into the bowl, helping to maintain critical flow. The tubing from the Blood Pump and the White Pump join to form one line entering the bowl.

Prime

During Prime in platelet protocols, the White Pump moves air from the reservoir or platelet bags to the plasma bag. This reduces the amount of air that needs to be expressed from the platelet product at the end of the procedure.

Draw

During Draw in platelet protocols that use the White Pump, the speed is set automatically according to the donor's hematocrit. The MCS+ device calculates the correct speed of the White Pump for each donor so that the critical flow is the same for each donor. If no plasma is available in the plasma bag (e.g., at the beginning of the first Draw), then the White Pump is inactive. When the Weigher detects plasma in the plasma bag, the White Pump is activated.

The MCS+ device also continuously controls the speed of the White Pump so that the critical flow remains constant even if the speed of the Blood Pump changes during the procedure. For example, if donor flow decreases and the Blood Pump speed decreases, the White Pump speed automatically increases to maintain the desired critical flow.

Surge

During Surge, the White Pump draws plasma out of the plasma bag and pumps it at high speed into the bowl to elutriate (wash out) platelets.

Return

During Return, the White Pump draws plasma from the plasma bag and mixes it in-line with red cells that are being drawn from the bowl by the Blood Pump. The plasma from the plasma bag and the red cells from the bowl mix at the manifold between the bowl and the pumps and then are pumped to the donor/patient through the Blood Pump.

Anticoagulant Pump

The Anticoagulant Pump turns only during Draw and Prime. During Draw, the pump delivers anticoagulant solution from the anticoagulant bag to the needle site. At the needle site, the anticoagulant is mixed with whole blood flowing from the donor/patient. The delivery and ratio of anticoagulant is regulated automatically, according to the selected protocol parameters.

During Prime, the Anticoagulant and Blood Pumps rotate simultaneously to prime the inlet side of the donor/patient harness with anticoagulant.

ANTICOAGULANT DRIP MONITOR

The anticoagulant drip monitor detects flow of anticoagulant during the Draw mode. In conjunction with the Anticoagulant Line Air Detector (ACAD), the drip monitor ensures flow of anticoagulant.

CENTRIFUGE

The disposable bowl is spun by the Centrifuge (Figure 2-11 and 2-12) to separate anticoagulated whole blood into its various components.

The Centrifuge operates in a range of 3,000 to 7,000 revolutions per minute (rpm). The most appropriate Centrifuge speed has been programmed for each protocol. Chapter 3, *Disposables*, explains how blood is separated in the spinning Centrifuge bowl.

There are two different types of centrifuge used in the MCS+ Systems. The centrifuge that is installed in your MCS+ System may utilize a mechanical system or a vacuum system to secure the bowl base during use. A "Mechanical Centrifuge" uses mechanical clips to secure the bowl base, while a "Vacuum Centrifuge" uses a vacuum system to secure the bowl base. The type of centrifuge used does not affect the performance of the MCS+ device.

The mechanical centrifuge is easily distinguished from the vacuum centrifuge.

The mechanical centrifuge cover latch mechanism only requires a one-quarter turn and a downward push to unlock the cover halves. The mechanical centrifuge also features six mechanical clips on the centrifuge chuck which secure the bowl base as the bowl is snapped into place.

The vacuum centrifuge cover latch mechanism requires several turns before the cover halves can be separated. The vacuum centrifuge also has an "L" shaped gasket on the centrifuge chuck to assist the vacuum system in securing the bowl base into place.

Warning! The silicone grease used in vacuum centrifuges should never be applied to a mechanical centrifuge. Do not grease any part of the mechanical centrifuge. If grease has been applied to the mechanical chuck, contact Haemonetics Field Service immediately.

Mechanical Chuck

The bowl is held in the Mechanical Centrifuge by six mechanical clips in the chuck. No tools are necessary to load the bowl. To load the bowl:

1. Center the bowl.
2. Push the bowl down until the bowl base snaps into place.
3. Swing the cover down, then squeeze the cover closed until the cover latch snaps up.
4. Lock the cover switch by turning the cover latch knob clockwise.

Warning! The bowl base must be firmly installed and evenly seated in the centrifuge chuck. If the centrifuge chuck spins with the bowl base not evenly seated, as indicated by bowl wobbling or noise, bowl damage will occur and the procedure must be discontinued.

Do not attempt to reseat the bowl or continue the procedure. Do not return the contents of the bowl to the donor. Contact Haemonetics Technical Hot Line at (800) 537-2802, and discard the bowl contents and disposable per the facility's SOP.

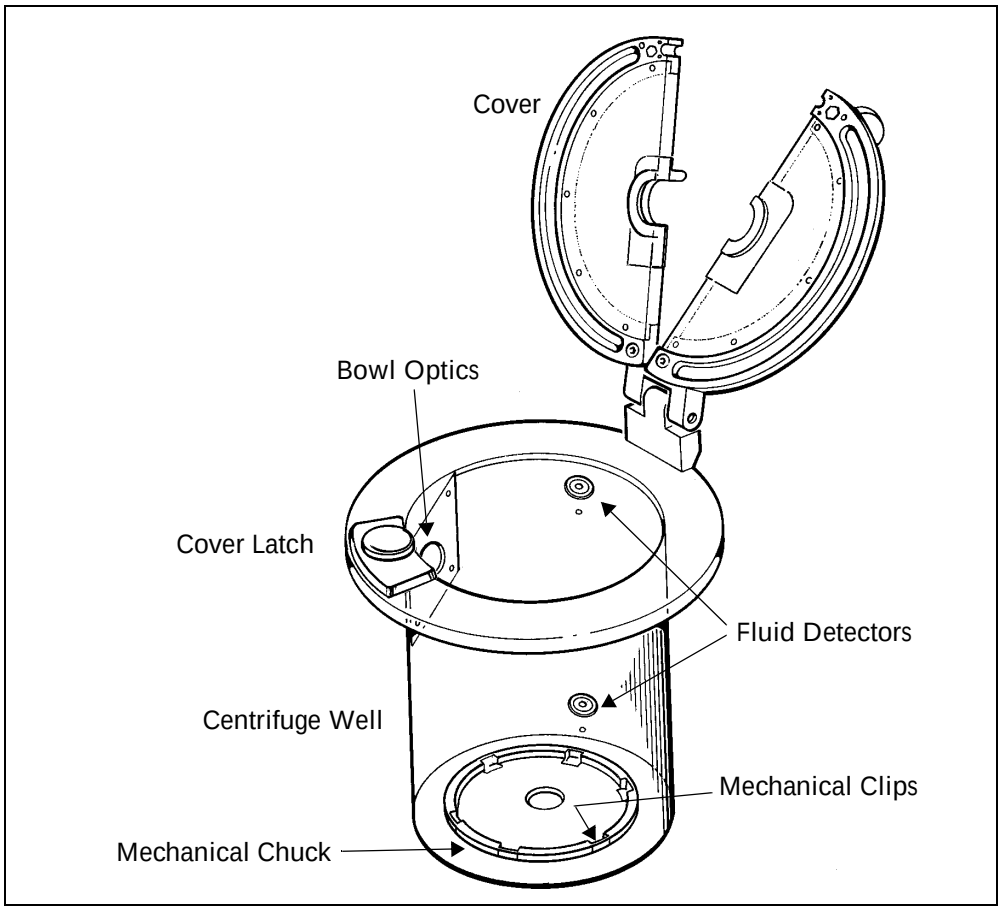


Figure 2-11, Mechanical Centrifuge Components

Vacuum Chuck

The bowl is held in the Vacuum Centrifuge Chuck by a vacuum that eliminates the need for additional tools and helps ensure proper loading of the bowl.

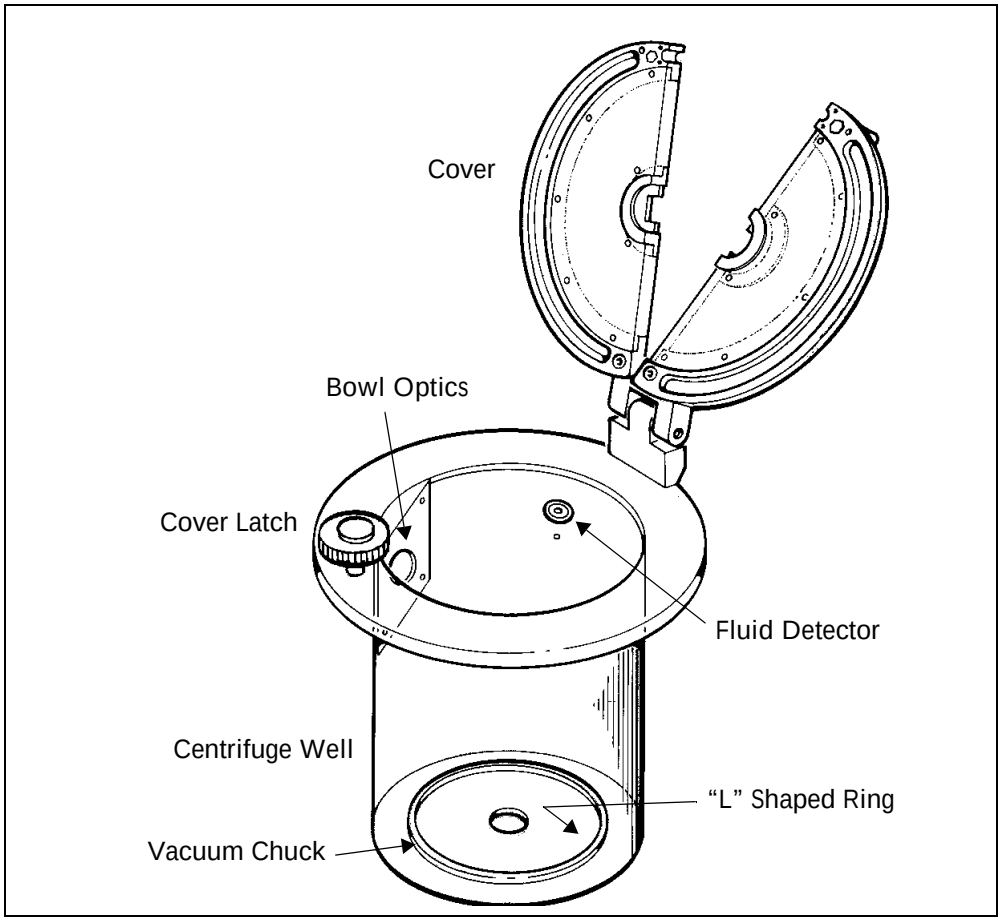


Figure 2-12, Vacuum Centrifuge Components

To load the bowl:

1. Center the bowl.
2. Push the bowl down until the vacuum chuck grips it firmly.
3. Close the cover and turn the cover latch knob clockwise to lock.

Warning! The bowl base must be firmly installed and evenly seated in the centrifuge chuck. If the centrifuge chuck spins with the bowl base not evenly seated, as indicated by bowl wobbling or noise, bowl damage will occur and the procedure must be discontinued.

Do not attempt to reseat the bowl or continue the procedure. Do not return the contents of the bowl to the donor. Contact Haemonetics Technical Hot Line at (800) 537-2802, and discard the bowl contents and disposable per the facility's SOP.

Manual Vacuum Release Button

The Manual Vacuum Release Button allows for emergency release of the centrifuge vacuum in MCS+ device units containing a vacuum centrifuge. Upon pressing the Vacuum Release Button, vacuum is bled off from the Centrifuge allowing the Centrifuge bowl to be removed. This may be necessary in the case of a power failure when the MCS+ device has not automatically released this vacuum. The Vacuum Release Button is located on the back panel of the MCS+ device.

Warning! At no time during routine machine operation should the Vacuum Release Button be pressed. Release of bowl suction during operation may cause damage to the Centrifuge bowl.

Bowl Optics Sensor

An Optical Sensor in the Centrifuge Well is aimed at the core of the bowl. As various components pass between the sensor and the core, the sensor measures the optical reflection from the blood in the bowl.

The bowl Optics Sensor detects the interface between the plasma and the buffy coat layers in the spinning bowl. The sensor initiates the surge collection of platelets, ends plasma collection, or signals the next step in therapeutic procedures. Refer to Chapter 3 for more detail.

Fluid Detectors

The Fluid Detectors, mounted in the wall of the Centrifuge, are responsible for stopping the Centrifuge and the pumps if fluid comes in contact with them.

Warning! A detection of fluid by the fluid detectors invalidates extended storage dating for single donor platelets.

LINE SENSOR

The Line Sensor, located on the MCS+ device deck to the right of the Centrifuge, monitors the density of the blood components in the effluent tubing after they exit the bowl.

PRESSURE CUFF

To assist in maintaining optimal venous flow, the MCS+ device has a Pressure Cuff that automatically maintains a preset pressure during the Draw mode. The pressure setting is adjustable. The Pressure Cuff automatically deflates when the machine enters the Return mode. The Pressure Cuff connects to the MCS+ device at a cuff connector on the rear panel of the cabinet.

The Pressure Cuff may be inflated and deflated by using the CUFF key on the Control Panel.

MACHINE ACCESSORIES

Each item described below is available for purchase; please consult a published price list or your Haemonetics Sales Representative for additional information. For protection and convenience, a transport case and a stand for use with the MCS+ device are available from Haemonetics.

List No. 9010 Transport Box

This accessory allows for safe transportation to any location necessary without the worry of damage to the machine. The box is durable and easy to clean and also allows for stacking to minimize the room needed to transport. The transport box doubles as a stand during machine operation.

List No. 7010 Machine Stand

The stand holds the MCS+ device securely during operation but allows for easy removal for maintenance.

SPECIFICATIONS

Dimensions (approximate)

In Operation

Height: 27 inches (68.5 cm)
Width: 22.25 inches (56.5 cm)
Depth: 22.25 inches (56.5 cm)

Closed

Height: 17.25 inches (44 cm)
Width: 22.25 inches (56.5 cm)
Depth: 13.38 inches (36.5 cm)

Weight

Approximately 56 lbs. (26.3 kg)

Power Requirements

Electrical voltage: 100/220~ VAC, ±10%, switch-selectable. (Proper voltage is set at the factory for the destination country.) Outlet must be properly grounded.

Operating frequency: 47–63 Hz

Input fusing rating: 5.0 amperes domestic
F2.5 amperes international

Main power cable detachable: <HAR>, VDE tested.

Machine Symbol Chart

Type BF

This symbol indicates that the applied portion of the device (the portion that contacts the donor) is electrically isolated and that the device has an internal electrical power source providing adequate protection against electrical shock, particularly regarding allowable leakage currents and reliability of the protective earth connection.

Alternating current

IPX1 **Protection against ingress of liquids**

Enclosure prevents entry of liquids that might interfere with the satisfactory and safe operation of the equipment.

Power off

Power on

Protective Earth

Attention (consult accompanying documents)

Fuse Symbol

Warning! Storage and transport conditions should be within the following range: 8% – 80% rh, -20°C – +50°C.

Warning! Requirements for working environment. Ambient temperature: 10°C to 27°C. Relative humidity rate: maximum 95%, noncondensing. There is an explosion risk if the machine is used in the presence of flammable anesthetics.

✍ *Note: Haemonetics recommends preventive maintenance by a Haemonetics service engineer or manufacturer-trained biomedical technician once per year (±30 days). A series of equipment and safety system checks will be performed to assure continued trouble-free performance.*

Chapter Three

DISPOSABLES

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GENERAL

The MCS®+ utilizes single-use disposable sets to separate and collect blood. All sets contain a processing chamber, the "bowl," and tubing and bags, the "harness."

DISPOSABLE SET STORAGE AND HANDLING

Store all disposables in a dry, well-ventilated area that is free from exposure to chemical vapors. Avoid contaminating the surface of disposable plastic components with chemicals by making sure that hands or gloves contacting the plastic surface are clean and dry.

Warning! Upon completion of any apheresis procedure, the used disposables should be considered biohazardous and should be handled pursuant to those policies and procedures dictated by your medical facility's Exposure Control Plan, as legally required by the OSHA Bloodborne Pathogen Standard.

The expiration date of the disposable set is noted on the package cover.

INSPECTION

Always inspect the disposable set as it is removed from the package. Be sure there are no kinks that might obstruct flow through the tubing. Minor imperfections do not interfere with blood flow or routine processing.

INSTALLATION

Installation of disposable sets is explained in detail in the appropriate protocol section.

✍ *Note: When handling clean disposables, either wash your hands or apply clean gloves before opening the protective packaging to eliminate the chance of powders or other deposits collecting on either machine or disposable component surfaces. This helps to ensure that the performance of the Optic Sensors is not adversely affected.*

BOWLS

Bowls are secured inside the Centrifuge and spun at high speed. Blood components and other solutions are separated according to their specific gravities.

The bell-shaped bowl used for cellular collections is called the Latham bowl (Figure 3-1), named after the inventor of the original Haemonetics centrifugal processing chamber, Allen Latham, Jr., the founder of Haemonetics Corporation.

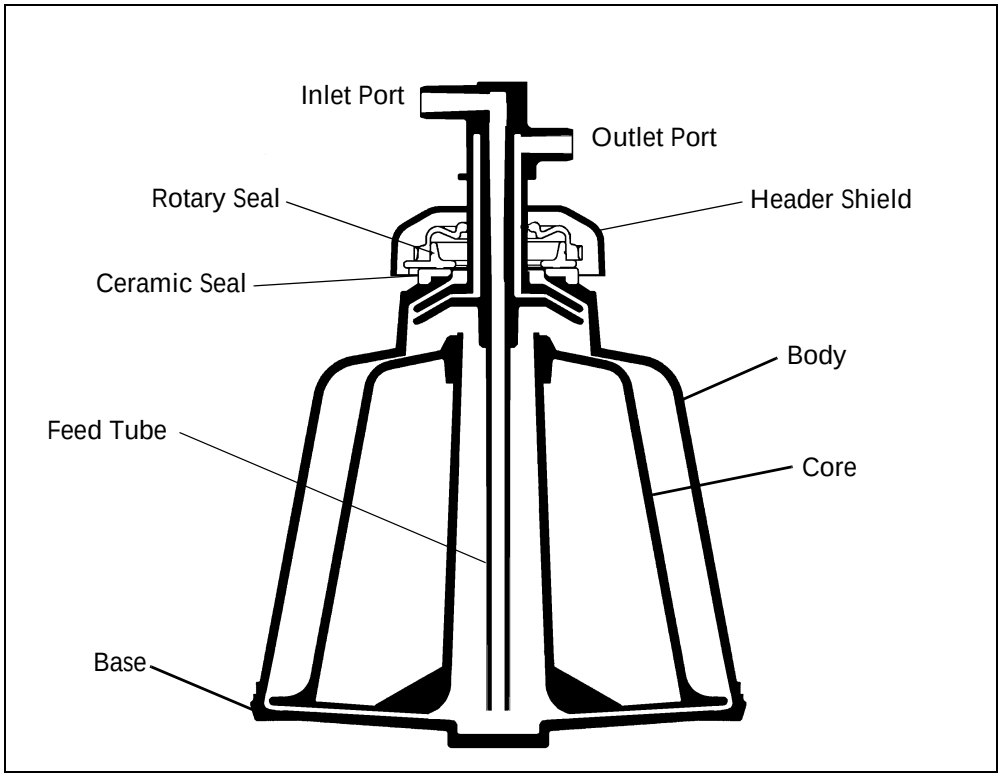

Figure 3-1, The Latham Disposable Blood Processing Bowl

Latham Bowl

How the Latham Bowl Works

The bowl consists of two parts: 1) a stationary section which includes an inlet, feed tube, effluent path, and outlet port and 2) a rotating section which consists of the processing chamber and the rotary seal.

The rotary seal provides a barrier between the sterile interior sections of the bowl and the outside environment. It is the only point within the Latham bowl structure where the stationary and rotating sections make contact.

During Draw (Figure 3-2), anticoagulated whole blood enters the inlet port and is directed down the feed tube to the bottom of the bowl. At this point, because of the presence of centrifugal forces generated by the spinning bowl, the fluid migrates to the outer periphery of the bowl. During this process, sterile air in the bowl is displaced into a collection bag.

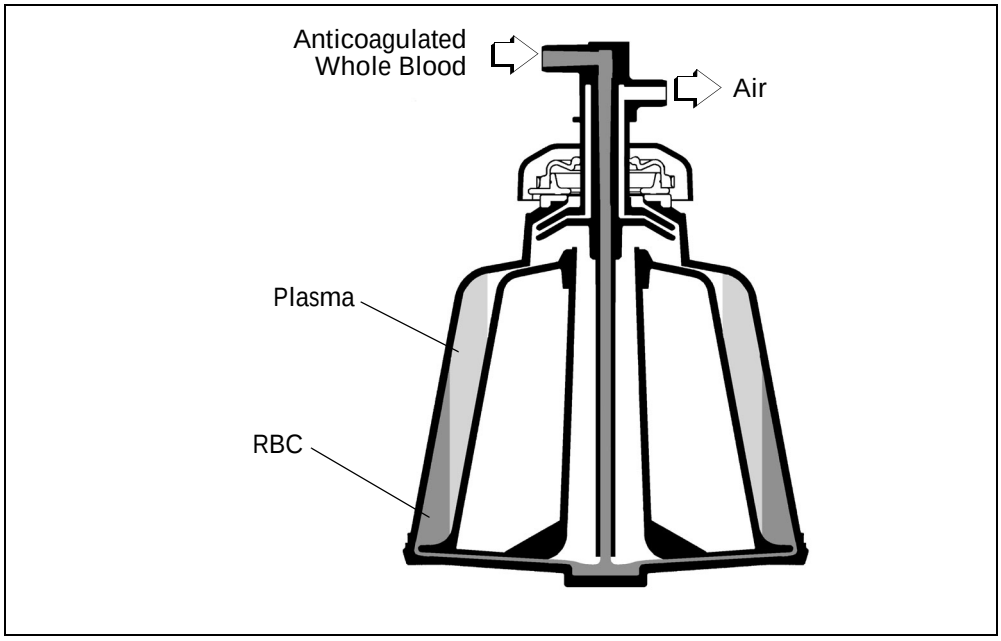

Figure 3-2, The Beginning of the Draw Mode

Centrifugation takes place as anticoagulated whole blood continues to enter the bowl. The blood component of the highest density, the red blood cells (RBCs), migrate to the outer wall of the bowl. In order of decreasing density, the white blood cells (WBCs), platelets, and plasma form vertical layers.

✍ *Note: The nature of centrifugal separation is such that the lines of definition between blood components are not distinct. A minimal contamination of an undesired component with the desired component is to be expected. For example, some platelets may be present in the plasma in a PLP procedure.*

When the bowl is filled, plasma, the lightest component (and therefore closest to the core) begins to overflow through the effluent path and outlet port (Figure 3-3).

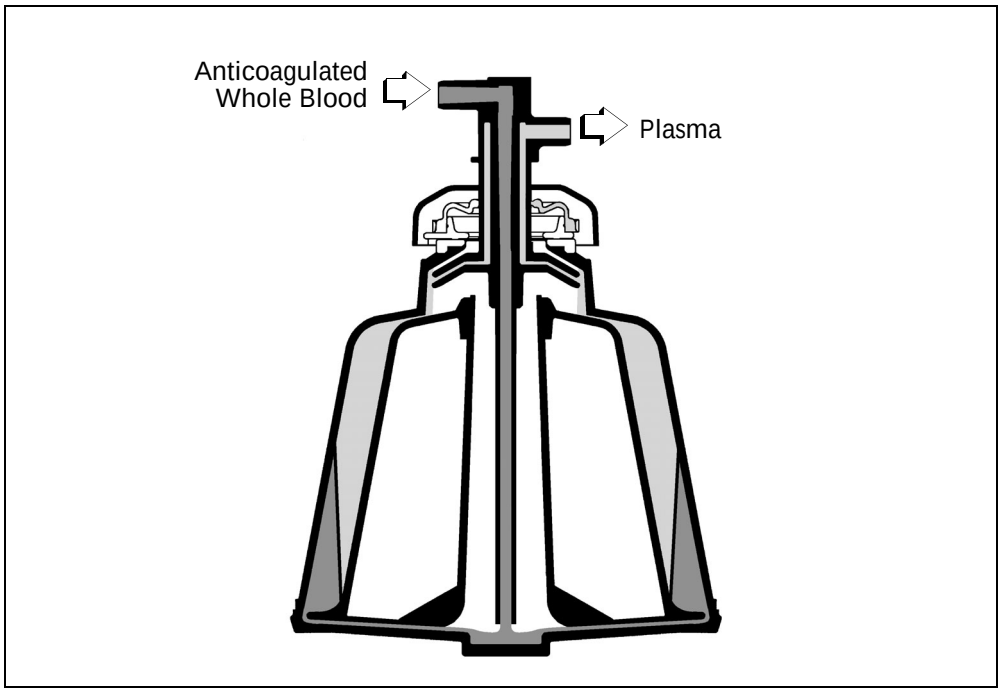

Figure 3-3, Plasma Overflow

Overflow continues until the desired component exits the bowl and is collected into a collection bag.

The Latham Bowl "Surge" Process

The "Surge" process is used in platelet collection protocols. Each cycle of the platelet protocols consists of a Draw and Return mode. Surge is part of the Draw mode.

After most of the plasma has exited the bowl, the buffy coat reaches the appropriate position within the bowl and is "detected" by the Bowl Optics sensor. Figure 3-4 shows when the buffy coat is detected by the Bowl Optics. This initiates the Surge phase of the protocols.

Surge is the elutriation (washing) of platelets away from the buffy coat. This is accomplished via high speed recirculation of plasma from the plasma bag back through the bowl.

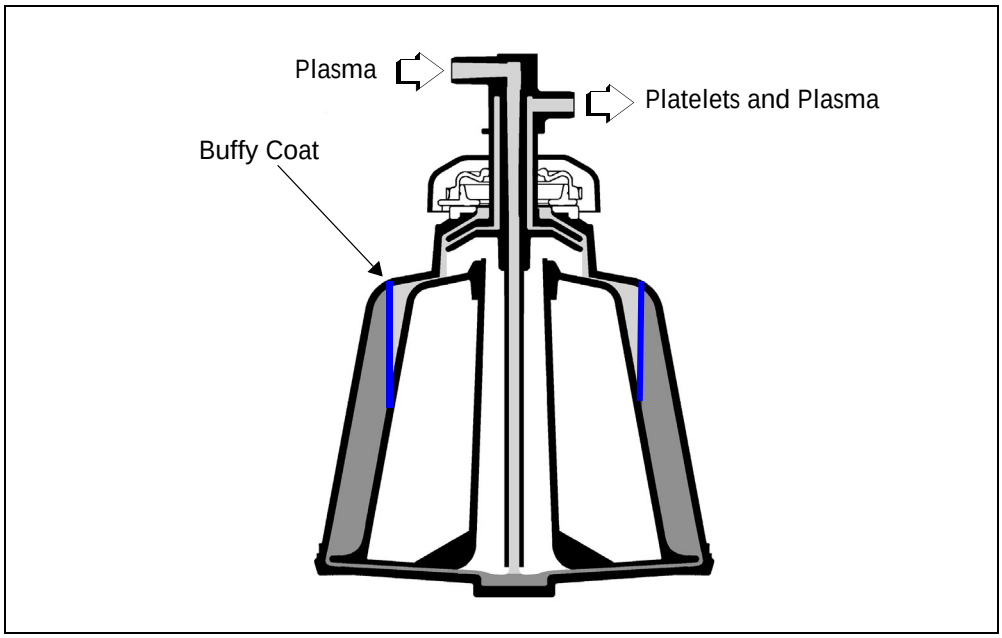

Figure 3-4, Surge Elutriation

Once the buffy coat is detected by the Bowl Optics sensor, plasma from the plasma bag is rapidly surged through the bowl.

The surging plasma quickly flows to the bottom outside edge of the spinning bowl. The plasma passes through the cell layers and increases the separation between them. The platelets, which are lighter, flow out of the bowl with the plasma while the heavier cells remain in the bowl.

Once collection is completed, the bowl stops spinning. Due to the loss of centrifugal force, the blood remixes.

When the bowl is spinning, it appears to be full. However, all Haemonetics bowls are designed with an inner core in which some sterile air is trapped during centrifugation. Once the bowl stops, the volume of blood within the processing chamber settles to the bottom and displaces the sterile air that was trapped within the inner core. This causes the stationary bowl to appear to be only two-thirds full.

Once the bowl stops spinning, the Blood Pump reverses and returns the remaining blood components to the donor, as shown in Figure 3-5.

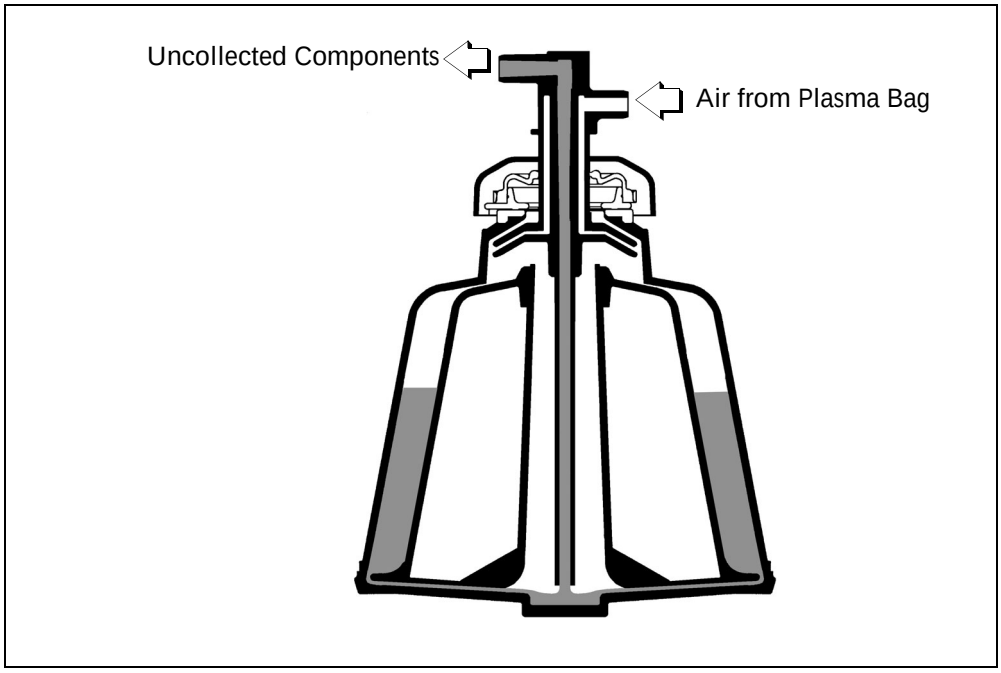

Figure 3-5, The Return Mode

The Role of the White Pump

In the platelet collection protocols, the White Pump pulls plasma from the plasma bag of the disposable set and pumps it into the bowl located within the Centrifuge. The tubing from the Blood Pump and the White Pump join into one line entering the bowl.

HARNESS COMPONENTS

Elements of the Harness

The elements of the harness used depend upon the component to be collected. Some of the typical elements of a set are described below.

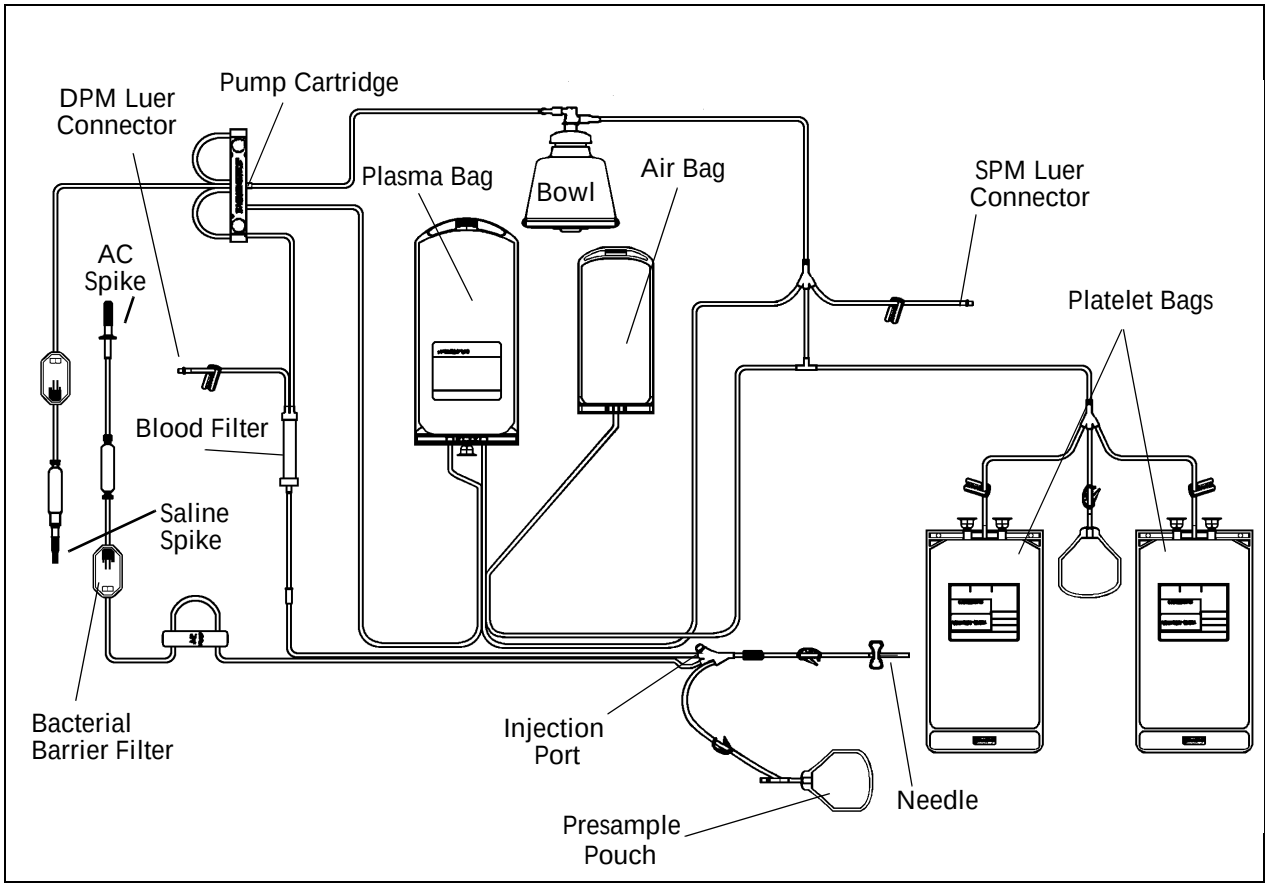

Figure 3-6, A Typical Disposable Set (LN 994 shown)

Pre-attached Needle

This needle prevents contamination from external sources that could occur before the needle and the needle adapter are connected.

Warning! If the needle is disconnected from the harness at any time during collection, the storage life of the platelet product is reduced to 24 hours.

Injection Port (near needle)

The injection port on the MCS+ device 5-day disposable sets is intended only for emergency situations requiring administration of fluids or drugs.

Warning! If the injection site is used before removing the platelet concentrate from the collection set, the storage life of the platelet product is reduced to 24 hours.

Presample Pouch

This pouch allows collection of donor blood samples without a separate venipuncture. The tubing must be sealed before sampling from the pouch and may not be reopened to the system without compromising extended dating.

Bacterial Filter

This 0.22μ filter is connected to the anticoagulant and saline lines of the disposable set. It prevents potential contaminants, which may be present as a result of manual connection of the fluid to the disposable, from passing from the fluid container into the MCS+ device disposable set. The flow of the fluid is not restricted.

✍ *Note: This filter allows the attachment of the AC or saline using a spike while still maintaining a functionally closed system and does not affect the extended dating of the product.*

Donor Pressure Monitor (DPM) Luer Connector

This element of the disposable contains a 0.22μ hydrophobic filter to prevent the infiltration of potential contaminants into the disposable. It is intended to be coupled with the receptor on the DPM to assist in the monitoring of pressures within the donor line from the venipuncture site to the bowl.

Warning! If, for any reason, the DPM filter becomes wet during the procedure, the MCS+ device is no longer able to monitor venous pressure. See Chapter 4, *Safety and Donor/Patient Care Precautions*.

✍ *Note: The DPM and SPM luer connectors do not need protective caps. Since these filters are bacteriostatic, the disposable remains a closed system.*

System Pressure Monitor (SPM) Luer Connector

This element of the disposable set contains a 0.22µ filter to prevent the infiltration of contaminants into the disposable. It is intended to be coupled with the receptor on the SPM to assist in the monitoring of pressures within the bowl.

Warning! If at any time during a collection, the SPM connector becomes wet, the MCS+ device may no longer be able to monitor pressure in the bowl.

Extended Storage Platelet Bags

These bags are designed to permit storage of platelet concentrate up to and through 5 days. The bags permit proper transfer of gases in order to maintain suitable storage conditions for platelets for an extended period of time.

✍ *Note: Platelet disposable sets designated by "-CPP" contain CPP platelet storage bags. A platelet bag made of CPP material can store up to 5.0 x 10^{11} platelets for five days with a maximum concentration of 2600 x 10^{6} platelets per ml. Platelet disposable sets without the designation "-CPP" contain CLX platelet storage bags. A platelet bag made of CLX material can store up to 3.5 x 10^{11} platelets for five days.*

Leukocyte Reduction Filter

This filter is an option integrated on platelet disposables (LN 994F and LN 994CF) to allow filtration of the platelet product prior to storage.

Biohazard Waste Bag

A biohazard waste bag is attached to the drain port on the Centrifuge Well. Should there be a fluid spill in the Centrifuge Well, this bag captures the fluid as it drains out the port.

A biohazard waste bag should be attached to the Centrifuge Drain at all times during machine operation. The bag must hang freely without tubing occlusions.

Warning! The provided biohazard waste bags are not intended for the collection and storage of transfusable products. Haemonetics recommends that you handle and dispose of these bags, once contaminated, pursuant to those policies and procedures dictated by your medical facility's Exposure Control Plan, as legally required by the OSHA Bloodborne Pathogen Standard.

Other Disposable Set Elements

Disposable sets for protocols that do not require extended dating may include other elements and may not include the previously listed elements.

Additional details about the disposable sets are included in the protocol chapters as well as in the *Directions for Use* that accompany each device.

Chapter Four

SAFETY AND DONOR/PATIENT CARE PRECAUTIONS

SAFETY PRECAUTIONS 4-2
- Storage and Handling of Disposables 4-2
- Flammable Locations 4-2
- Electrical Shock Hazards 4-2
- Rotating Machinery 4-3
- Communicable Disease 4-3
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SAFETY PRECAUTIONS

This section outlines precautions that must be taken in order to ensure safe operation of the MCS+ device.

Storage and Handling of Disposables

Many plastics are sensitive to chemicals such as solvents, refrigerants, and detergents. Under particularly adverse conditions of exposure to solvent vapors, the mechanical properties of plastics may be seriously degraded.

In managing the inventory of stored disposables, apply the first-in, first-out (FIFO) technique to minimize the length of storage for any unit.

Warning! Store all disposables in a dry, well-ventilated area that is free from exposure to chemical vapors. Avoid contaminating the surface of disposable plastic components with chemicals by making sure that hands or gloves contacting the plastic surface are clean and dry.

Flammable Locations

The MCS+ device is intended to be used in locations that are free of flammable gases and vapors.

Warning! The MCS+ device should never be used in the presence of flammable agents. Refer to National Fire Prevention Association No. 56A, pages 14 and 76.

Electrical Shock Hazards

Inside the MCS+ device cabinet, there are various electrical terminal strips and other components. Personal contact with any of these components while the power is connected could result in electrical shock. Thus, the panels should not be
removed without first turning off and unplugging the machine.

Warning! Have leakage current tested regularly.

Leakage current indicates an electrical shock hazard from direct contact with any exposed portion of the equipment. Each instrument is carefully checked during final inspection to verify that leakage current is less than 100 microamperes at 110 VAC and less than 500 microamperes at 220 VAC.

The owner should have a current leakage test performed regularly to ensure that the machine continues to meet the 100/500 microampere or less standard. Particular attention should be given to current leakage after an event such as a saline spill or major voltage surge in the house electrical system. See Chapter Six.

In view of the high conductivity of electrolytes, always avoid touching any portion of the system with wet hands. Always work with clean, dry hands.

Rotating Machinery

It must be recognized that even small, rapidly rotating parts have enough dynamic energy to cause severe injury if any part of the person or clothing gets caught in them. As a safety feature, the MCS+ device is equipped with a trip mechanism that stops the Centrifuge if the cover is open.

Warning! Persons operating this equipment or working nearby should take the standard precautions applicable to all rotating machinery.

Communicable Disease

Despite the application of all available tests to screen for communicable diseases, such as hepatitis, HIV, or syphilis, there is always the risk that the blood being processed is infected. Treat all blood as though it were infected; always clean up spilled blood immediately.

Restrictions to Flow

Warning! No restriction to flow can be permitted in the effluent line.

If the outlet port is inadvertently clamped off, pressure builds up in the processing chamber to such an extent that the rotary seal is raised like a safety valve to release pressure. This results in the loss of the pocket of trapped air and the contamination of the rotary seal faces with supernatant. Depending upon the nature of the supernatant, the functional characteristics of the rotary seal may become altered. Heating and wear effects may become quite noticeable, and in this case, the contents of the bowl cannot be considered appropriate for reinfusion.

Warning! Avoid blocking any tubing carrying blood from the pump. A buildup of pressure in this tubing can result in the wide dispersal of blood.

Observe the waste bag to verify that the accumulation of air in the air bag is not being prevented by either a flow restriction or an air leak.

Twists and Kinks in Tubing

After loading the harness set on the machine, a careful recheck of the loaded disposable set should be completed to make certain that each section is in the correct position on the machine and that all tubing is free of twists or kinks. Twists and kinks in the tubing can result in hemolysis with high levels of plasma hemoglobin.

Chapter Five

NOTICE MESSAGES AND TROUBLESHOOTING

PROCESS MESSAGES 5-2
INTERLOCK MESSAGES 5-2
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RECOVERY PROCEDURE 5-5
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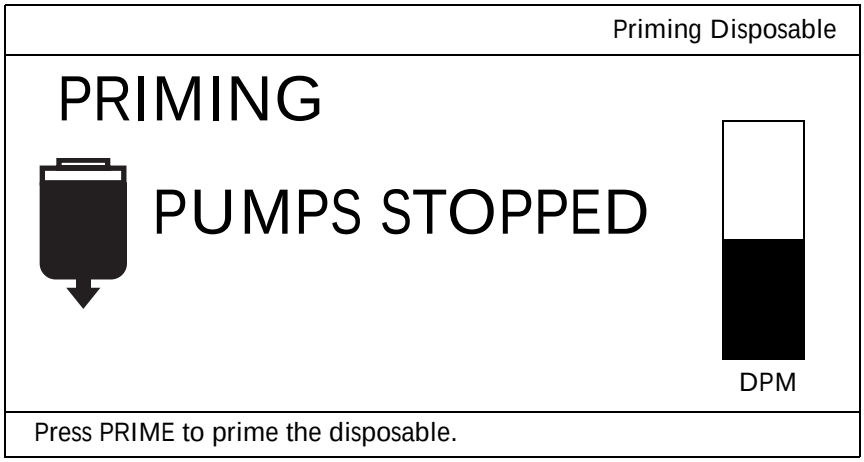
PROCESS MESSAGES

During normal operation, the MCS®+ provides information on the progress of a protocol. Process messages are displayed as a normal part of system operation. Donor pressure is continually displayed, as is the current operating mode (Prime, Draw, or Return). A typical process message is shown below.

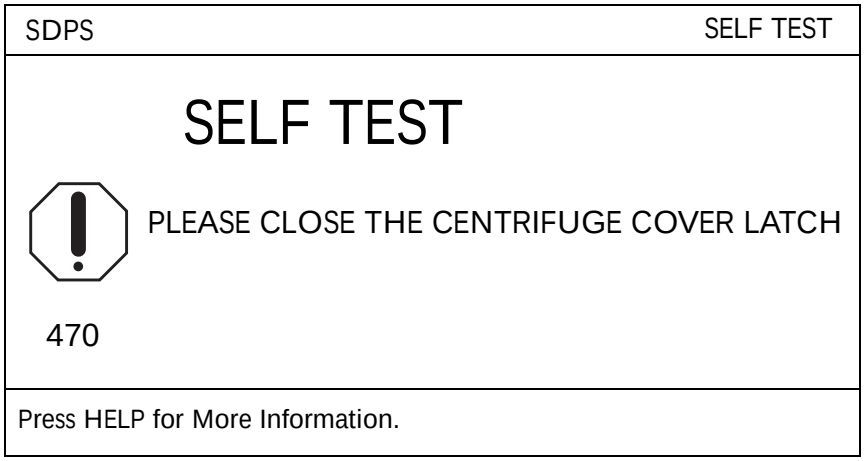


Note in the above display that the current mode is indicated (“PRIMING”), the current state of the machine is shown (“PUMPS STOPPED”), the donor pressure is displayed (on the bar graph), and the next step for the operator is suggested (“Press PRIME to prime the disposable.”).

INTERLOCK MESSAGES

As a part of normal operation, the MCS+ device monitors the components’ system interlocks, such as the Centrifuge Cover, the Protocol Card door, the Donor Pressure Monitor, and the System Pressure Monitor.

For example, as part of the power-on self test, the following display is shown.

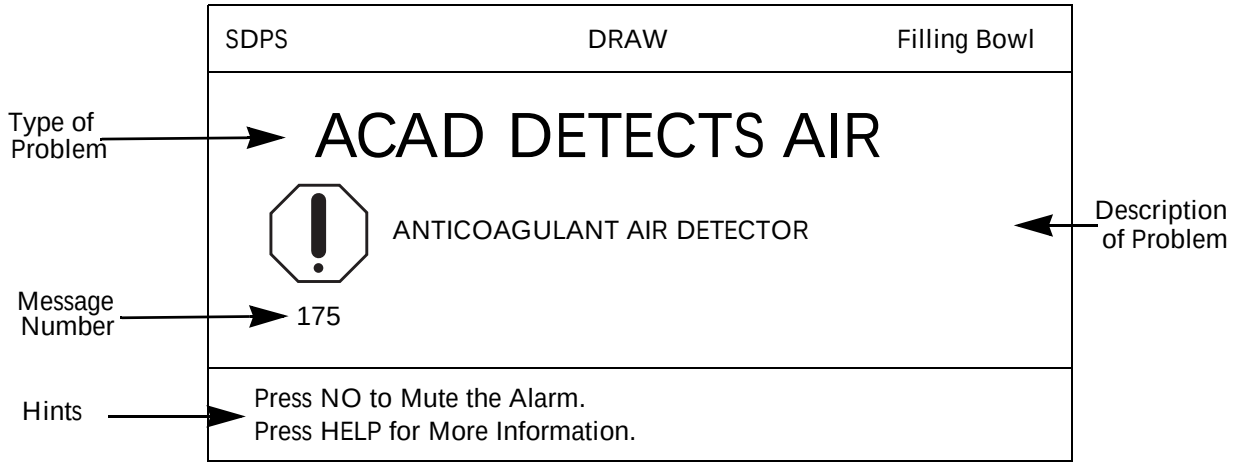


In order for the MCS+ device to pass this interlock test, the operator must open and close the Centrifuge Cover. This confirms that the interlock on the Centrifuge Cover is functioning properly.

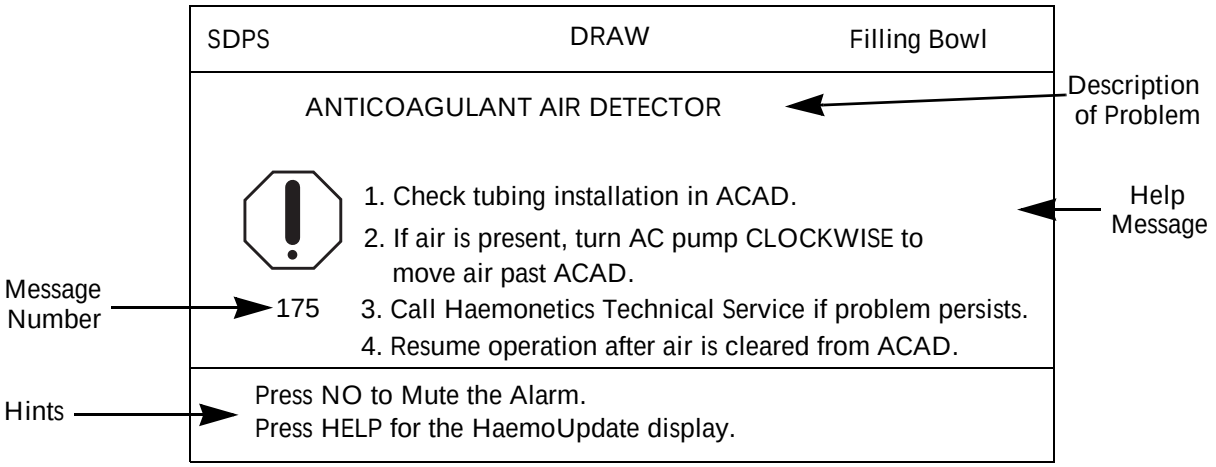
Through the interlock messages, the system monitors the integrity of both the machine and the disposable.

NOTICE MESSAGES

Notice messages may be initiated by one of two systems that are monitoring the MCS+ device at all times during operation. Generally, notice messages are indications of situations that can easily be corrected by the operator.



If an error condition occurs, the operator should record the message number for later reference. The operator does not have to record the notice text (in the above example, this is “ACAD Detects Air ”). Pressing NO mutes the alarm for a period of up to one minute, and pressing HELP displays a Help screen with further troubleshooting hints. A typical Help screen is shown below.

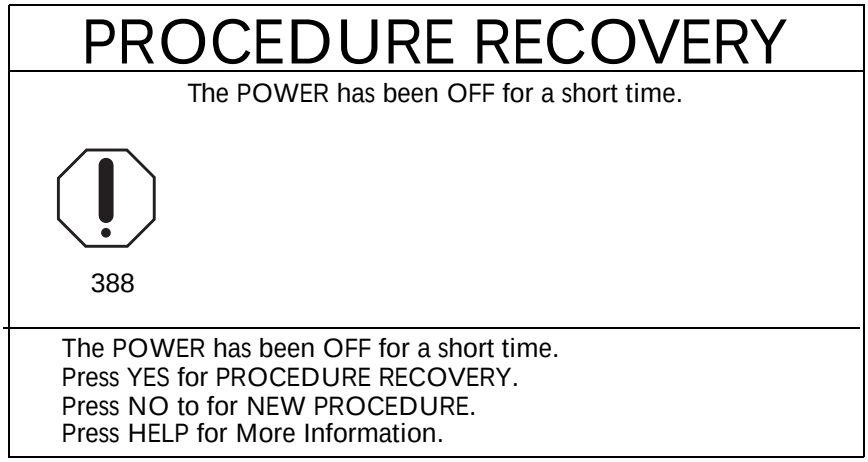

SDPS
DRAW
Filling Bowl
ANTICOAGULANT AIR DETECTOR
Description of Problem
1. Check tubing installation in ACAD.
2. If air is present, turn AC pump CLOCKWISE to move air past ACAD.
3. Call Haemonetics Technical Service if problem persists.
4. Resume operation after air is cleared from ACAD.
Help Message
Message Number
175
Hints
Press NO to Mute the Alarm.
Press HELP for the HaemoUpdate display.

Automatic monitoring of the MCS+ device begins the moment the system is powered on. The first action of the MCS+ device is to test its own components and ensure that the correct disposable set has been installed properly.

Failure of the self-test halts the test sequence. Should this occur, record the test failure message, power off the machine, and power on. If the problem persists, contact a Haemonetics Field Service Engineer.

RECOVERY PROCEDURE

If, for any reason, the system has been powered off or reset during a procedure, the following screen will be displayed:


PROCEDURE RECOVERY
The POWER has been OFF for a short time.
388
The POWER has been OFF for a short time.
Press YES for PROCEDURE RECOVERY.
Press NO to for NEW PROCEDURE.
Press HELP for More Information.

To perform a procedure recovery, the disposable can remain fully installed. The MCS+ device will resume the current procedure after the YES key has been pressed. At this time further information on how to perform a procedure recovery is available in the on-line help screen. Full procedure statistics in the HaemoUpdate screen can be retrieved by pressing the HELP key twice. Once the MCS+ device has performed its self-tests, the MCS+ device can be guided through the centrifuge cover testing and disposable installation. Upon successful completion of the self-tests and disposable installation, the procedure may be resumed by pressing the RETURN key. The MCS+ device will now resume the procedure by returning the contents of the bowl and any additional plasma to the donor or patient.

REPEAT VENIPUNCTURE

When continued blood flow through the needle is no longer possible due to an infiltration or any other cause, it may be desirable to return any red cells remaining in the bowl. The following procedure allows for changing needles, performing a second venipuncture, returning any blood remaining in the disposable and either continuing or discontinuing the collection procedure. The collection targets (Number of platelets, volume of plasma, etc.) for the procedure may not have been met. Refer to the HaemoUpdate screen for current product information.

✍ *Note: Haemonetics recommends that a 16g needle with tubing extension is used to ensure optimal flow conditions.*

1. Hermetically seal the needle line close to the needle.
2. When applicable, remove the product bags per the procedures given in the appropriate section of the applicable protocol manual.

✍ *Note: Removal of the product bags is required only when repeat venipuncture results in violation of the required storage conditions. For example, the product bags should be removed if the repeat venipuncture will result in an open system for platelet collections and product storage of greater than 24 hours is required.*

3. Disconnect the donor per local SOPs.
4. Replace the needle with a new needle using one of the two methods outlined below.

   Method A: Using aseptic technique.

   a. Disconnect the needle from the disposable at the Luer connector.
   b. Attach new needle to disposable.

✍ *Note: This method utilizes an open system and may reduce the storage of collected products to 24 hours, depending on the product collected.*

   Method B: Using a Sterile Connection Device.

   a. Using a sterile connection device, attach a new needle to the disposable.

✍ *Note: Depending on the site SOPs, this technique may result in retention of full product storage duration. To retain full storage duration, it is imperative that the needle line is hermetically sealed between needle and location of sterile connection.*

5. Perform venipuncture per local SOP.
6. Remove all hemostats from the disposable.
7. Continue the procedure as follows: Press the DRAW key and observe air from needle pass through the DLAD1 and DLAD2 into the blood filter. Depending on how full the bowl is, the MCS+ device may give the warning “DRAW not allowed, Press RETURN to continue.” When this message occurs, press the STOP key, followed by the DRAW key. The MCS+ device will then initiate the Draw mode.
8. Once the air from the needle has reached the bowl, press RETURN to allow blood and plasma to return to the donor.
9. Allow all blood and plasma to return to the donor.

In case the procedure is to be discontinued:

10. Once all blood has been returned and the MCS+ device initiates the next Draw mode, press the STOP key to discontinue the procedure. Press the HELP key to enter the HaemoUpdate screen and obtain procedure statistics.

In case the procedure is to be continued:

11. Allow the MCS+ device to continue the procedure per standard procedures.

GRAVITY REINFUSION PROCEDURE

In the rare event that it is not possible to automatically return the blood in the disposable (e.g., power outage), and it is deemed necessary to return the red cells from the bowl, use the following procedure. The collection targets (Number of platelets, volume of plasma, etc.) for the procedure may not have been met. Refer to the HaemoUpdate screen for current product information. In case of a general power loss, this information may be retrieved by performing a procedure recovery when power has been restored. The disposable does not need to remain on the machine. To retrieve the information, press HELP at the "Install Disposable" screen for procedure statistics.

✍ *Note: To maintain 5-day storage of platelet products, the platelet product must be hermetically sealed and removed from the disposable prior to removing the venipuncture needle. Refer to the appropriate procedures given in the Protocol Manual for sealing and removing the platelet bags.*

1. Hemostat the donor line near the needle.
2. Remove white-striped tubing from white valve, or applicable line to bag containing the air from the bowl.
3. Remove the product bags per the procedures given in the appropriate section of the applicable protocol manual (platelet and plasma procedures only).
4. Remove the red-striped tubing from the Red Valve.
5. Remove white cartridge and Blood and White Pump tubing.
6. Release the hemostat near needle and observe flow from bowl to needle. Roll air bag to assist flow. If flow slows or stops, remove bowl from centrifuge and hold upright higher than donor's heart to facilitate flow.
7. Continue to infuse until all blood is returned and then clamp the donor line and remove needle.
8. Press the HELP key to enter the HaemoUpdate screen to obtain applicable statistics.
9. Record per local SOP.

Table 5-1, Notice Messages*

#	*Notice Messages*	*Help Messages*
0	**SYSTEM PROBLEM** THE COMPUTER HAS ENCOUNTERED AN ERROR.	A CPU error caused the MCS+ device to reset. 1. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
5	**BLAD DETECTS AIR** BLOOD LINE AIR DETECTOR	BLOOD LINE AIR DETECTOR 1. Check tubing installation in BLAD. 2. Check donor line for flow restriction. 3. Resume operation after air is cleared from BLAD.
6	**DLAD1 DETECTS AIR** DONOR LINE AIR DETECTOR 1	DONOR LINE AIR DETECTOR 1 1. Check tubing installation in DLAD1. 2. If air has traveled past DLAD1 or DLAD2, open the RED valve and turn the BLOOD pump CLOCKWISE to move air into the bowl. 3. Resume operation after air is cleared from tubing back to bowl.
7	**DLAD2 DETECTS AIR** DONOR LINE AIR DETECTOR 2	DONOR LINE AIR DETECTOR 2 1. Check tubing installation in DLAD2. 2. If air has traveled past DLAD1 or DLAD2, open the RED valve and turn the BLOOD pump CLOCKWISE to move air into the bowl. 3. Resume operation after air is cleared from tubing back to bowl.
15 thru 24	**SYSTEM PROBLEM** THE COMPUTER HAS ENCOUNTERED AN ERROR.	A CPU error caused the MCS+ device to reset. 1. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
25	**CENTRIFUGE PROBLEM** THE CENTRIFUGE IS NOT TURNING.	1. Check that bowl is installed properly. 2. Check that Centrifuge rotates freely. 3. Check header of bowl. 4. Resume operation. NOTE: If problem persists, call Haemonetics Technical Hot Line.
26	**CENTRIFUGE PROBLEM** THE CENTRIFUGE WAS TURNING TOO FAST.	1. Wait until Centrifuge has stopped. 2. Check Centrifuge for obstructions. 3. Resume operation. NOTE: If problem persists, call Haemonetics Technical Hot Line.

*Platelet protocols in Platelet Protocol Software Version E or later have revised notice messages and associated message numbers. Refer to Appendix C of the Platelet Protocol Manual, Part Number 51052-00 for details.

#	*Notice Messages*	*Help Messages*
27	**CENTRIFUGE PROBLEM** THE CENTRIFUGE VACUUM IS NOT DETECTED.	The vacuum is too low to hold the bowl. 1. Remove bowl from the Centrifuge. 2. Re-seat bowl. 3. Ensure that bowl is properly seated. 4. Resume operation.
28	**SYSTEM PROBLEM** FLUID HAS BEEN DETECTED IN THE CENTRIFUGE.	A leak may have occurred. This procedure MUST be discontinued! 1. Discontinue the procedure. 2. Note the condition of the disposable before disposing of it. 3. Contact Haemonetics Technical Hot Line. *NOTE: The disposable should be returned to Haemonetics for analysis*.
29 30	**SYSTEM PROBLEM** THE COMPUTER HAS ENCOUNTERED AN ERROR.	A CPU error caused the MCS+ device to reset. 1. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
31	**CENTRIFUGE PROBLEM** THE CENTRIFUGE SPEED WAS TOO SLOW.	1. Wait until Centrifuge has stopped. 2. Check that bowl is installed properly. 3. Check Centrifuge for obstructions. 4. Resume operation. NOTE: If problem persists, call Haemonetics Technical Hot Line.
32 thru 36	**SYSTEM PROBLEM** THE COMPUTER HAS ENCOUNTERED AN ERROR.	A CPU error caused the MCS+ device to reset. 1. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
37	**AIR DETECTED BY** AIR DETECTED BY SYSTEM MONITOR.	The Air Detector detects air. 1. Check tubing installation in detector. 2. Turn AC or Blood Pump CLOCKWISE to remove air. 3. Resume operation.
38	**SYSTEM PROBLEM** THE COMPUTER HAS ENCOUNTERED AN ERROR.	A CPU error caused the MCS+ device to reset. 1. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
39	**CENTRIFUGE PROBLEM** THE CENTRIFUGE SPEED WAS TOO SLOW.	1. Wait until Centrifuge has stopped. 2. Check that bowl is installed properly. 3. Check Centrifuge for obstructions. 4. Resume operation. NOTE: If problem persists, call Haemonetics Technical Hot Line.

#	*Notice Messages*	*Help Messages*
40	**PUMP PROBLEM** AC PUMP WAS TURNING TOO SLOW.	A restriction may have occurred. 1. Check pump for restrictions. 2. Check pump for kinked tubing. 3. Resume operation.
41	**PUMP PROBLEM** BLOOD PUMP WAS TURNING TOO SLOW.	A restriction may have occurred. 1. Check pump for restrictions. 2. Check pump for kinked tubing. 3. Resume operation.
42	**PUMP PROBLEM** WHITE PUMP WAS TURNING TOO SLOW.	A restriction may have occurred. 1. Check pump for restrictions. 2. Check pump for kinked tubing. 3. Resume operation.
44	**PUMP PROBLEM** AC PUMP WAS TURNING TOO FAST.	A restriction may have occurred. 1. Check pump for restrictions. 2. Check pump for kinked tubing. 3. Resume operation.
45	**PUMP PROBLEM** BLOOD PUMP WAS TURNING TOO FAST.	A restriction may have occurred. 1. Check pump for restrictions. 2. Check pump for kinked tubing. 3. Resume operation.
46	**PUMP PROBLEM** WHITE PUMP WAS TURNING TOO FAST.	A restriction may have occurred. 1. Check pump for restrictions. 2. Check pump for kinked tubing. 3. Resume operation.
48	**PUMP PROBLEM** AC PUMP WAS TURNING IN THE WRONG DIRECTION.	A restriction may have occurred. 1. Check pump for restrictions. 2. Check pump for kinked tubing. 3. Resume operation.
49	**PUMP PROBLEM** BLOOD PUMP WAS TURNING IN THE WRONG DIRECTION.	A restriction may have occurred. 1. Check pump for restrictions. 2. Check pump for kinked tubing. 3. Resume operation.
50	**PUMP PROBLEM** WHITE PUMP WAS TURNING IN THE WRONG DIRECTION	A restriction may have occurred. 1. Check pump for restrictions. 2. Check pump for kinked tubing. 3. Resume operation.
52	**PUMP PROBLEM** AC PUMP POSITION IS NOT CORRECT.	A restriction may have occurred. 1. Check pump for restrictions. 2. Check pump for kinked tubing. 3. Resume operation.
53	**PUMP PROBLEM** BLOOD PUMP POSITION IS NOT CORRECT	A restriction may have occurred. 1. Check pump for restrictions. 2. Check pump for kinked tubing. 3. Resume operation.

#	*Notice Messages*	*Help Messages*
54	**PUMP PROBLEM** WHITE PUMP POSITION IS NOT CORRECT.	A restriction may have occurred. 1. Check pump for restrictions. 2. Check pump for kinked tubing. 3. Resume operation.
56	**PUMP PROBLEM** THE AC/BLOOD PUMP RATIO IS INCORRECT.	An occlusion may have occurred at the Blood Pump or AC Pump. 1. Check both pumps for occlusions. 2. Resume operation.
57	**PUMP PROBLEM** THE AC/BLOOD PUMP RATIO IS INCORRECT.	An occlusion may have occurred at the Blood Pump or AC Pump. 1. Check both pumps for occlusions. 2. Resume operation.
58	**VALVE PROBLEM** THE RED VALVE WAS DETECTED OUT OF POSITION.	1. Toggle the valve manually. 2. Resume operation. NOTE: If problem persists, call Haemonetics Technical Hot Line.
61	**SYSTEM PROBLEM** THE COMPUTER HAS ENCOUNTERED AN ERROR.	A CPU error caused the MCS+ device to reset. 1. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
62	**ECV LIMIT** THE DONOR ECV LIMIT IS REACHED.	The allowed Extracorporeal Volume (ECV) limit was reached. A complete Return cycle must be performed. 1. Press RETURN to continue.
63	**SYSTEM PROBLEM** THE SAFETY SYSTEM HAS ENCOUNTERED AN ERROR.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
64	**SYSTEM PROBLEM** THE SAFETY SYSTEM HAS ENCOUNTERED AN ERROR.	A Watchdog error caused the MCS+ device to reset. 1. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
65	**SYSTEM PROBLEM** THE SAFETY SYSTEM HAS ENCOUNTERED AN ERROR.	A DPM/SPM connector caused the MCS+ device to reset. 1. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
66	**SYSTEM PROBLEM** THE SAFETY SYSTEM HAS ENCOUNTERED AN ERROR.	A pressure error caused the MCS+ device to reset. 1. Check installation of DPM and SPM. 2. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.

#	*Notice Messages*	*Help Messages*
67	**SYSTEM PROBLEM** THE SAFETY SYSTEM HAS ENCOUNTERED AN ERROR.	An Air Detector caused the MCS+ device to reset. 1. Check tubing installation in detectors. 2. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
68	**SYSTEM PROBLEM** THE SAFETY SYSTEM HAS ENCOUNTERED AN ERROR.	A State Fault caused the MCS+ device to reset. 1. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
69	**SYSTEM PROBLEM** THE SAFETY SYSTEM HAS ENCOUNTERED AN ERROR.	An ECV limit caused the MCS+ device to reset. 1. Check tubing installation at Blood Pump. 2. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
70	**SYSTEM PROBLEM** THE SAFETY SYSTEM HAS ENCOUNTERED AN ERROR.	A pump ratio caused the MCS+ device to reset. 1. Check tubing installation at Blood Pump. 2. Check tubing installation at AC Pump. 3. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
71	**SYSTEM PROBLEM** THE SAFETY SYSTEM HAS ENCOUNTERED AN ERROR.	A pump motor caused the MCS+ device to reset. 1. Check tubing installation at all pumps. 2. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
72	**SYSTEM PROBLEM** THE SAFETY SYSTEM HAS ENCOUNTERED AN ERROR.	A prime error caused the MCS+ device to reset. 1. Check tubing installation at all pumps. 2. Check proper installation of disposable. 3. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
73	**SYSTEM PROBLEM** THE SAFETY SYSTEM HAS ENCOUNTERED AN ERROR.	A power interruption caused the MCS+ device to reset. 1. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
74 thru 94	**SYSTEM PROBLEM** THE COMPUTER HAS ENCOUNTERED AN ERROR.	A CPU error caused the MCS+ device to reset. 1. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.

#	*Notice Messages*	*Help Messages*
100	**CENTRIFUGE PROBLEM** CENTRIFUGE SAFETY SWITCH NOT OPERATIONAL.	The centrifuge safety switch must be operational to operate the MCS+ device. 1. Power off, and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
101	**PROCESS PROBLEM** RETURN CYCLE TAKING TOO LONG.	Emptying bowl took longer than expected. An occlusion may have occurred. 1. Check tubing at pumps and bowl. 2. Check bowl. 3. Resume operation.
102	**PROCESS PROBLEM** BLAD DETECTED AIR EARLIER THAN EXPECTED.	BLAD DETECTED AIR EARLIER THAN EXPECTED 1. Check tubing installation in BLAD. 2. Open the RED valve and turn the BLOOD pump CLOCKWISE to move air into the bowl. 3. Resume operation after air is cleared from tubing back to bowl.
103	**NO AC FLOW** LOW AC FLOW DETECTED BY DRIP MONITOR.	1. Check that the AC bag contains fluid. 2. Check AC tubing for occlusions. 3. Check AC tubing for clamps. 4. Check Drip Chamber installation. 5. Check Drip Chamber fluid level. 6. Resume operation.
104	**NO AC FLOW** HIGH AC FLOW DETECTED BY DRIP MONITOR.	1. Check tubing at AC Pump. 2. Check Drip Chamber installation. 3. Check Drip Chamber fluid level. 4. Resume operation.
105	**NO AC FLOW** NO AC FLOW DETECTED BY DRIP MONITOR.	1. Check that the AC bag contains fluid. 2. Check donor tubing for occlusions. 3. Check donor tubing for closed clamps. 4. Check AC tubing for occlusions. 5. Check AC tubing for closed clamps. 6. Resume operation.
106	**SYSTEM PROBLEM** NO CUFF PRESSURE DETECTED.	1. Check that cuff is attached. 2. Check cuff for leaks. 3. Resume operation.
107	**PROCESS PROBLEM** NO AIR / PLASMA INTERFACE DETECTED.	1. Check pump tubing installation. 2. Check tubing for occlusions. 3. Check venipuncture. 4. Press RETURN to continue.
175	**ACAD DETECTS AIR** ANTICOAGULANT AIR DETECTOR	ANTICOAGULANT AIR DETECTOR 1. Check tubing installation in ACAD. 2. If air is present, turn AC pump CLOCKWISE to move air past ACAD. 3. Call Haemonetics Technical Service if problem persists. 3. Resume operation after air is cleared from ACAD.

#	*Notice Messages*	*Help Messages*
223	**CENTRIFUGE PROBLEM** THE CENTRIFUGE COVER IS NOT LOCKED.	1. Close Centrifuge Cover. 2. Tighten cover knob completely. 3. Resume operation.
224	**VALVE PROBLEM** THE PURPLE VALVE WAS DETECTED OUT OF POSITION.	1. Toggle the valve manually. 2. Resume operation. NOTE: If problem persists, call Haemonetics Technical Hot Line.
225	**VALVE PROBLEM** THE ORANGE VALVE WAS DETECTED OUT OF POSITION	1. Toggle the valve manually. 2. Resume operation. NOTE: If problem persists, call Haemonetics Technical Hot Line.
226	**VALVE PROBLEM** THE BLUE VALVE WAS DETECTED OUT OF POSITION.	1. Toggle the valve manually. 2. Resume operation. NOTE: If problem persists, call Haemonetics Technical Hot Line.
227	**VALVE PROBLEM** THE YELLOW VALVE WAS DETECTED OUT OF POSITION	1. Toggle the valve manually. 2. Resume operation. NOTE: If problem persists, call Haemonetics Technical Hot Line.
228	**VALVE PROBLEM** THE WHITE VALVE WAS DETECTED OUT OF POSITION.	1. Toggle the valve manually. 2. Resume operation. NOTE: If problem persists, call Haemonetics Technical Hot Line.
229	**VALVE PROBLEM** THE GREEN VALVE WAS DETECTED OUT OF POSITION.	1. Toggle the valve manually. 2. Resume operation. NOTE: If problem persists, call Haemonetics Technical Hot Line.
248 thru 252	**SYSTEM PROBLEM** THE COMPUTER HAS ENCOUNTERED AN ERROR.	A CPU error caused the MCS+ device to reset. 1. Power off and complete a Procedure Recovery. NOTE: If problem persists, call Haemonetics Technical Hot Line.
254	**VALVE PROBLEM** THE RED VALVE WAS DETECTED OUT OF POSITION.	1. Toggle the valve manually. 2. Resume operation. NOTE: If problem persists, call Haemonetics Technical Hot Line.
255	**CONNECTOR** THE DPM FILTER HAS BEEN DISCONNECTED.	Please install the filter. 1. Attach filter. 2. Ensure that the filter is not wet. 3. Resume operation.
256	**CONNECTOR** THE SPM FILTER HAS BEEN DISCONNECTED.	Please install the filter. 1. Attach filter. 2. Ensure that the filter is not wet. 3. Resume operation.

#	*Notice Messages*	*Help Messages*
257	**PRESSURE PROBLEM** HIGH PRESSURE ERROR AT THE DPM.	The DPM high pressure limit was exceeded. 1. Check tubing for occlusions. 2. Check tubing for closed clamps. 3. Check tubing at valves. 4. Check tubing at pumps. 5. Resume operation.
258	**PRESSURE PROBLEM** LOW PRESSURE ERROR AT THE DPM.	The DPM low pressure limit was exceeded. 1. Check tubing for occlusions. 2. Check tubing for closed clamps. 3. Check tubing at valves. 4. Check tubing at pumps. 5. Resume operation.
259	**PRESSURE PROBLEM** SPM HIGH PRESSURE ERROR.	The SPM high pressure limit was exceeded. 1. Check tubing for occlusions. 2. Check tubing for closed clamps. 3. Check tubing at valves. 4. Relieve pressure by opening WHITE valve. NOTE: The product shelf life becomes 24 hrs if the SPM filter is wet.
260	**PRESSURE PROBLEM** THE SPM PRESSURE WAS TOO LOW.	The SPM low pressure limit was exceeded. 1. Check tubing for occlusions. 2. Check tubing for closed clamps. 3. Check tubing at valves. 4. Check that product bags have not collapsed.
261	**PROCESS PROBLEM** DRAW not allowed, press RETURN to continue.	Cycle was interrupted with a full bowl. The MCS+ device cannot achieve re-separation. Press RETURN to continue.
262	**DOOR OPEN** THE PROTOCOL CARD DOOR IS OPEN.	1. Close the Protocol Card door. 2. Resume operation. NOTE: DO NOT remove/insert cards during operation of the MCS+ device.
263	**CENTRIFUGE PROBLEM** THE CENTRIFUGE COVER IS NOW LOCKED.	
264	**DOOR CLOSED** THE PROTOCOL CARD DOOR IS CLOSED.	1. Ensure the door stays closed. 2. Continue operation. NOTE: DO NOT remove/insert cards during operation of the MCS+ device.
265	**SYSTEM PROBLEM** PUMP MANIFOLD NOT INSTALLED.	The white pump manifold is not snapped in place. 1. Snap manifold in place. 2. Check pump tubing installation. 3. Resume operation.

#	*Notice Messages*	*Help Messages*
331	**BLAD DETECTS AIR** BLOOD LINE AIR DETECTOR	BLOOD LINE AIR DETECTOR 1. Check tubing installation in BLAD. 2. Check donor line for flow restriction. 3. Resume operation after air is cleared from BLAD.
340	**AIR REMOVED** AIR REMOVED FROM THE AIR DETECTOR.	The Air Detector detects fluid. 1. Check tubing for residual air. 2. Resume operation.
341	**NO FLOW** NO FLOW FROM THE DONOR IS DETECTED.	Caused by high pressure or vacuum at DPM. 1. Check donor tubing for occlusions. 2. Check donor tubing for closed clamps. 3. Check venipuncture. 4. Relieve pressure. 5. Resume operation.
343	**SYSTEM PROBLEM** NO PRESSURE CHANGE DETECTED AT DPM.	The DPM cannot detect venous pressure change. 1. Check the DPM tubing for occlusions. 2. Check the DPM tubing for clamps. 3. Ensure the DPM filter is dry. 4. Resume operation.
344	**SYSTEM PROBLEM** NO PRESSURE CHANGE DETECTED AT THE SPM.	1. Check the SPM tubing for occlusions. 2. Check the SPM tubing for clamps. 3. Ensure the SPM filter is dry. 4. Resume operation. NOTE: The product shelf life becomes 24 hours if the SPM filter is wet.
345	**PRESSURE PROBLEM** THE DPM PRESSURE IS OUT OF RANGE.	1. Close needle clamp. 2. Open RED valve. 3. Turn Blood Pump CLOCKWISE. 4. Resume operation.
351	**NO FLOW** PRIME FLOW CONTROL PROBLEM.	Caused by high pressure or vacuum at DPM. 1. Check donor tubing for occlusions. 2. Check donor tubing for closed clamps. 3. Check venipuncture. 4. Relieve pressure. 5. Resume operation.
352	**NO FLOW** RETURN FLOW CONTROL PROBLEM.	Caused by high pressure or vacuum at DPM. 1. Check donor tubing for occlusions. 2. Check donor tubing for closed clamps. 3. Check venipuncture. 4. Relieve pressure. 5. Resume operation.
369	**NOTICE** THE AC BAG MAY BE ALMOST EMPTY.	The AC bag may be almost empty. 1. Check the AC bag and replace if necessary. 2. Resume operation.

#	*Notice Messages*	*Help Messages*
372	**SYSTEM PROBLEM** THE PROTOCOL CARD DOES NOT MATCH DISPOSABLE.	The installed Protocol Card and disposable do not match. 1. Check that the correct disposable is installed. 2. Check that the correct Protocol Card is inserted. 3. Clean the disposable ID window.
373	**PRESSURE PROBLEM** NO DONOR PRESSURE CHANGE DETECTED AT THE DPM.	The DPM cannot detect venous pressure change. 1. Check the DPM tubing for occlusions 2. Check the DPM tubing for clamps 3. Ensure the DPM filter is dry. 4. Resume operation.
374	**PRESSURE PROBLEM** NO SYSTEM PRESSURE CHANGE DETECTED AT THE SPM.	1. Check the SPM tubing for occlusions. 2. Check the SPM tubing for clamps. 3. Ensure the SPM filter is dry. 4. Resume operation. NOTE: The product shelf life becomes 24 hrs if the SPM filter is wet.
375	**ACAD AIR REMOVED** ANTICOAGULANT AIR DETECTOR	ANTICOAGULANT AIR DETECTOR 1. Check tubing installation in ACAD. 2. If air is present, turn AC pump CLOCKWISE to move air past ACAD. 3. Call Haemonetics Technical Service if problem persists. 4. Resume operation after air is cleared from ACAD.
376	**BLAD AIR REMOVED** BLOOD LINE AIR DETECTOR	BLOOD LINE AIR DETECTOR 1. Check tubing installation in BLAD. 2. Check donor line for flow restriction. 3. Open the RED valve and turn the BLOOD pump CLOCKWISE to move air into the bowl. 4. Resume operation after air is cleared from BLAD.
377	**DLAD1 AIR REMOVED** DONOR LINE AIR DETECTOR 1	DONOR LINE AIR DETECTOR 1 1. Check tubing installation in DLAD1. 2. If air has traveled past DLAD1 or DLAD2, open the RED valve and turn the BLOOD pump CLOCKWISE to move air into the bowl. 3. Resume operation after air is cleared from tubing back to bowl.
378	**DLAD2 AIR REMOVED** DONOR LINE AIR DETECTOR 2	DONOR LINE AIR DETECTOR 2 1. Check tubing installation in DLAD2. 2. If air has traveled past DLAD1 or DLAD2, open the RED valve and turn the BLOOD pump CLOCKWISE to move air into the bowl. 3. Resume operation after air is cleared from tubing back to bowl.

#	*Notice Messages*	*Help Messages*
379	**WEIGHER PROBLEM** EXPECTED FLUID FLOW TO WEIGHER NOT DETECTED.	No change in bag weight was detected. 1. Check that bags are properly installed. 2. Check tubing for occlusions. 3. Check tubing at valves. 4. Resume operation.
380	**WEIGHER PROBLEM** EXPECTED FLUID FLOW FROM WEIGHER NOT DETECTED.	No change in bag weight was detected. 1. Check that bags are properly installed. 2. Check tubing for occlusions. 3. Check tubing at valves. 4. Resume operation.
381	**MAXIMUM COLLECTION NOMOGRAM TO BE EXCEEDED** Press RETURN to decrease the product volumes and remain within the nomogram. Press YES to collect the target product volumes, overriding the nomogram.	The FDA Nomogram limit will be reached. Decide whether to follow the nomogram and limit the product volumes or to override the FDA nomogram. 1. Press RETURN to follow the FDA nomogram. 2. Press YES to override the FDA nomogram.
387	**WEIGHER PROBLEM** THE WEIGHT OF THE BAGS ON THE WEIGHER CHANGED.	An unexpected weight change occurred. Do NOT touch the Weigher during operation. 1. Check that the bag hangs free. 2. Check tubing at valves. 3. Resume operation.
388	**PROCEDURE RECOVERY** The POWER has been OFF for a short time.	A recovery sequence can be performed to CONTINUE the last procedure if desired, or a NEW procedure may be initiated.
389	**PROCESS PROBLEM** RETURN CYCLE WAS NOT COMPLETED.	The bowl is not empty. 1. Press RETURN to complete return cycle. 2. Press STOP to stop draw cycle. 3. Press DRAW to start draw cycle.
390	**PROCESS PROBLEM** INCOMPLETE CYCLE. NO PRODUCT COLLECTED.	No platelets were collected this cycle. The cycle was interrupted early. 1. Press RETURN to continue.
393	**ECV MAX** THE DONOR ECV LIMIT IS REACHED	The maximum allowed Extracorporeal Volume (ECV) limit was reached. A complete Return cycle must be performed. 1. Press RETURN to continue.
394	**ECV LIMIT** xx% TBV Reached – Return Now?	The Extracorporeal Volume (ECV) limit was reached. Decide whether to continue to Draw or to start Return. 1. Press DRAW to keep drawing. 2. Press RETURN to go into return.

#	*Notice Messages*	*Help Messages*
395	**SYSTEM PROBLEM** THE EFFLUENT TUBING IS NOT INSTALLED	The effluent tubing may not be installed. 1. Check tubing at Yellow valve. 2. Check tubing at White valve. 3. Check tubing at Green valve. 4. Check slide clamp at SPM. 5. Resume operation.
396	**SYSTEM PROBLEM** THE PRODUCT BAG IS CLAMPED	The tubing to the product bag is clamped. 1. Check tubing at Green valve. 2. Check tubing for closed clamps. 3. Check tubing for kinks. 4. Resume operation.
397	**BOWL TYPE MISMATCH**	A different bowl size was detected. Confirm whether the MCS+ device detected the correct bowl: 1. Press YES to accept the new bowl size and continue. 2. Press NO to keep the existing bowl size and continue.
398	**PROCESS PROBLEM** IS THE BUFFY BAG EMPTY?	Air has been detected at the BLAD, indicating that the Buffy Bag may be empty. 1. Press YES to confirm and switch to donor. or 2. Press NO to continue to draw from Buffy Bag.
399	**PROCESS PROBLEM** IS THE BUFFY BAG EMPTY?	Air has been detected at the BLAD, but the Buffy Bag should be empty. 1. Press YES to confirm and switch to donor. or 2. Press NO to continue to draw from Buffy Bag.
400	**SELF TEST PROBLEM** THE COMPUTER CPU TEST FAILED.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
402	**SELF TEST PROBLEM** THE COMPUTER ROM CRC TEST FAILED.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
404	**SELF TEST PROBLEM** THE PROTOCOL CARD CRC TEST FAILED.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
405	**SELF TEST PROBLEM** THE CALIBRATION CRC TEST FAILED.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
406	**SELF TEST PROBLEM** THE CONFIGURATION CRC TEST FAILED.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.

#	*Notice Messages*	*Help Messages*
407	**NOTICE** THE PROTOCOL CARD DOES NOT MATCH DISPOSABLE.	The installed Protocol Card and disposable do not match. 1. Check that the correct disposable is installed. 2. Check that the correct Protocol Card is inserted. 3. Clean the disposable ID window.
408	**SELF TEST PROBLEM** ANTICOAGULANT AIR DETECTOR (ACAD) TEST FAILED.	Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
409	**SELF TEST PROBLEM** BLOOD LINE AIR DETECTOR (BLAD) TEST FAILED.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
410	**SELF TEST PROBLEM** DONOR LINE AIR DETECTOR 1 (DLAD1) TEST FAILED.	Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
411	**SELF TEST PROBLEM** DONOR LINE AIR DETECTOR 2 (DLAD2) TEST FAILED.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
413	**VALVE PROBLEM** PURPLE VALVE SELF TEST FAILED.	1. Toggle the valve manually. 2. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
414	**VALVE PROBLEM** ORANGE VALVE SELF TEST FAILED.	1. Toggle the valve manually. 2. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
415	**VALVE PROBLEM** RED VALVE SELF TEST FAILED.	1. Toggle the valve manually. 2. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
416	**VALVE PROBLEM** BLUE VALVE SELF TEST FAILED.	1. Toggle the valve manually. 2. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
417	**VALVE PROBLEM** YELLOW VALVE SELF TEST FAILED.	1. Toggle the valve manually. 2. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
418	**VALVE PROBLEM** WHITE VALVE SELF TEST FAILED.	1. Toggle the valve manually. 2. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.

#	*Notice Messages*	*Help Messages*
419	**VALVE PROBLEM** GREEN VALVE SELF TEST FAILED.	1. Toggle the valve manually. 2. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
420	**SELF TEST PROBLEM** A/D CONVERTER 20% TEST FAILED.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
421	**SELF TEST PROBLEM** A/D CONVERTER 50% TEST FAILED.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
422	**SELF TEST PROBLEM** A/D CONVERTER 80% TEST FAILED.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
423	**SELF TEST PROBLEM** PLEASE CLAMP THE DPM LINE AND REMOVE FILTER.	During self test, the DPM and SPM filters can not be installed. 1. Clamp tubing to the appropriate filter. 2. Remove filter from connector. 3. Resume operation.
424	**SELF TEST PROBLEM** PLEASE CLAMP THE SPM LINE AND REMOVE FILTER.	During self test, the DPM and SPM filters can not be installed. 1. Clamp tubing to the appropriate filter. 2. Remove filter from connector. 3. Resume operation.
425	**SELF TEST PROBLEM** Please install the DPM Filter.	Please install the filter. 1. Attach filter. 2. Ensure that the filter is not wet. 3. Resume operation.
426	**SELF TEST PROBLEM** Please install the SPM Filter.	Please install the filter. 1. Attach filter. 2. Ensure that the filter is not wet. 3. Resume operation.
427	**SELF TEST PROBLEM** THE DPM CONNECTOR TEST FAILED.	The MCS+ device could not detect the pressure monitor filter was removed. 1. Remove pressure filter from connector. 2. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
428	**SELF TEST PROBLEM** THE SPM CONNECTOR TEST FAILED.	The MCS+ device could not detect the pressure monitor filter was removed. 1. Remove pressure filter from connector. 2. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.

#	*Notice Messages*	*Help Messages*
429	**SELF TEST PROBLEM** THE DPM IS OUT OF TOLERANCE.	The Pressure Monitor signal is out of the allowed range. 1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
430	**SELF TEST PROBLEM** THE SPM IS OUT OF TOLERANCE.	The Pressure Monitor signal is out of the allowed range. 1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
431	**SELF TEST PROBLEM** THE WEIGHER IS OUT OF TOLERANCE.	The Weigher signal is out of the allowed range. 1. Remove all weight from Weigher. 2. Extend Weigher arm. 3. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
432	**SELF TEST PROBLEM** THE CUFF IS OUT OF TOLERANCE.	The Cuff pressure is out of the allowed range. 1. Check cuff tubing for occlusions. 2. Check the cuff connection. 3. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
433 434	**SELF TEST PROBLEM** THE SAFETY SYSTEM FAILED THE SELF TEST.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
435	**SELF TEST PROBLEM** THE LINE SENSOR OUTPUT IS TOO LOW.	1. Remove tubing from Line Sensor. 2. Check Line Sensor for contamination. 3. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
436	**SELF TEST PROBLEM** THE LINE SENSOR OUTPUT IS TOO HIGH.	1. Remove tubing from Line Sensor. 2. Check Line Sensor for contamination. 3. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
437 438	**SELF TEST PROBLEM** THE SAFETY SYSTEM FAILED THE SELF TEST.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
439	**SELF TEST PROBLEM** LOW PRESSURE ERROR AT THE DPM.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.

#	*Notice Messages*	*Help Messages*
440	**SELF TEST PROBLEM** LOW PRESSURE ERROR AT THE DPM.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
442	**SELF TEST PROBLEM** HIGH PRESSURE ERROR AT THE DPM.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
443	**SELF TEST PROBLEM** STATE TEST ON CHANNEL 1 FAILED.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
444	**SELF TEST PROBLEM** STATE TEST ON CHANNEL 2 FAILED.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
447	**SELF TEST PROBLEM** TIME BASE TEST ON CHANNEL 1 FAILED.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
448	**SELF TEST PROBLEM** TIME BASE TEST ON CHANNEL 2 FAILED.	1. Turn power OFF, then ON and try again NOTE: If problem persists, call Haemonetics Technical Hot Line.
449 452 453	**SELF TEST PROBLEM** THE SAFETY SYSTEM FAILED THE SELF TEST.	1. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
454	**VALVE PROBLEM** PURPLE VALVE MAY NOT BE LOADED.	The disposable test indicates that the valve may not be loaded. 1. Check tubing installation at valve. 2. Resume operation.
455	**VALVE PROBLEM** ORANGE VALVE MAY NOT BE LOADED.	The disposable test indicates that the valve may not be loaded. 1. Check tubing installation at valve. 2. Resume operation.
456	**VALVE PROBLEM** RED VALVE MAY NOT BE LOADED.	The disposable test indicates that the valve may not be loaded. 1. Check tubing installation at valve. 2. Resume operation.
458	**VALVE PROBLEM** WHITE VALVE MAY NOT BE LOADED.	The disposable test indicates that the valve may not be loaded. 1. Check tubing installation at valve. 2. Resume operation.
459	**VALVE PROBLEM** YELLOW VALVE MAY NOT BE LOADED.	The disposable test indicates that the valve may not be loaded. 1. Check tubing installation at valve. 2. Resume operation.

#	*Notice Messages*	*Help Messages*
460	**VALVE PROBLEM** GREEN VALVE MAY NOT BE LOADED.	The disposable test indicates that the valve may not be loaded. 1. Check tubing installation at valve. 2. Resume operation.
461	**SELF TEST PROBLEM** THE CENTRIFUGE VACUUM SYSTEM IS OBSTRUCTED.	Centrifuge vacuum could not be released. 1. Remove bowl. 2. Check that white filter in Centrifuge Chuck base is dry. 3. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
462	**SELF TEST PROBLEM** DISPOSABLE ID READER FAILED SELF TEST.	1. Remove white pump manifold. 2. Clean disposable ID reader window. 3. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
466	**WEIGHER PROBLEM** PLEASE REMOVE ALL WEIGHT FROM WEIGHER.	1. Remove any weight on Weigher. 2. Resume operation. 3. Replace bag AFTER self test.
467	**SELF TEST PROBLEM** PLEASE DISCONNECT THE CUFF FROM REAR PANEL.	Excessive Cuff pressure was measured. 1. Disconnect cuff from rear panel. 2. Deflate cuff completely. 3. Connect cuff to rear panel. 4. Resume operation.
468	**SELF TEST PROBLEM** IS LINE SENSOR CLEAN AND TUBING REMOVED?	1. Remove tubing from Line Sensor. 2. Check Line Sensor for contamination. 3. Turn power OFF, then ON and try again. NOTE: If problem persists, call Haemonetics Technical Hot Line.
469	**SELF TEST** Please OPEN the Centrifuge Cover Latch.	The Centrifuge Cover Switch must be tested for safe operation. 1. OPEN and CLOSE the Centrifuge Cover Switch as requested.
470	**SELF TEST** Please CLOSE the Centrifuge Cover Latch.	The Centrifuge Cover Switch must be tested for safe operation. 1. OPEN and CLOSE the Centrifuge Cover Switch as requested.
471	**NOTICE** THE PROTOCOL PARAMETERS HAVE BEEN RESET.	The saved protocol parameters have been reset. Before starting the next procedure: 1. Reprogram the HaemoCalculator. 2. Reprogram Modify.
—	**SOFTWARE WATCHDOG** INVALID ID.	The computer has sensed an invalid Software Watchdog ID code. Please turn the power off and contact Haemonetics Technical Hot Line.

#	*Notice Messages*	*Help Messages*
—	**SOFTWARE WATCHDOG** INVALID ID SEQUENCE.	The computer has sensed an incorrect Software Watchdog ID sequence. Please turn the power off and contact Haemonetics Technical Hot Line.
—	**SOFTWARE WATCHDOG** ID TIMEOUT.	The computer has sensed a Software Watchdog ID timeout. Please turn the power off and contact Haemonetics Technical Hot Line.
—	**SOFTWARE WATCHDOG** NOT ENABLED.	The computer has sensed that the Software Watchdog was not enabled. Please turn the power off and contact Haemonetics Technical Hot Line.

Chapter Six

MAINTENANCE

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GENERAL

The MCS®+ devise requires minimal maintenance. Most maintenance will consist of cleaning the system. A record of the type and date of maintenance performed should be kept. Haemonetics also recommends that a full preventive maintenance checkup be performed annually by a Haemonetics Service Representative or qualified biomedical engineer to ensure maximum machine performance.

✍ *Note: A tool kit consisting of the following items has been included with each MCS+ device: Allen wrench (to remove the pump rotors from the pump assembly), Phillips screwdriver, brush (to remove any loose debris from within the roller assembly), and silicone grease (to periodically lubricate Vacuum Centrifuge "L" Shaped Ring).*

Warning! Do not grease any part of the Mechanical Centrifuge. If grease has been applied to the mechanical chuck, contact Haemonetics Field Service immediately.

MAINTENANCE AND CLEANING

Normal maintenance of the MCS+ device consists only of seeing that spilled blood and wash solutions are immediately cleaned. up and that the Vacuum Centrifuge "L" Shaped Ring is greased monthly or as needed with frequent use.

Warning! Do not grease any part of the Mechanical Centrifuge. If grease has been applied to the mechanical chuck, contact Haemonetics Field Service immediately.

✍ *Note: If the mechanical chuck becomes contaminated with blood, call Haemonetics Technical Hot Line at (800) 537-2802.*

A spray bottle for cleaning the Centrifuge is recommended. A cleaning kit, consisting of a spray bottle, lint-free gauze, and cleaning solution, should be available at all times. The following supplies are needed:

- Tool kit
- Clear, warm water
- Cleaning solutions (10% bleach and water plus other cleaning solution)
- Lint-free cloth or towels
- Spray bottle
- Protective gloves

All blood spills should be cleaned immediately, pursuant to those policies and procedures dictated by your medical facility's Exposure Control Plan, as legally required by the OSHA Bloodborne Pathogen Standard. If there is no institutional policy for decontamination in place, use the recommended method as follows: clean and decontaminate the blood spill with 10% bleach solution applied by lint-free gauze.

When any Haemonetics product (equipment or disposables) that has been used during a procedure is returned to Haemonetics for any reason, you must decontaminate and repackage the product in compliance with the medical facility's Exposure Control Plan and U.S. Department of Transportation regulations for interstate shipping of blood-contaminated products.

Warning! Disconnect electrical power from the MCS+ device before servicing the system to prevent potential danger of electrical shock.

Warning! Haemonetics recommends handling all biologically contaminated materials pursuant to those policies and procedures dictated by your medical facility's Exposure Control Plan, as legally required by the OSHA Bloodborne Pathogen Standard.

Centrifuge Maintenance

There are two different types of centrifuge used in the MCS+ Systems. The centrifuge that is installed in your MCS+ System may utilize a mechanical system or a vacuum system to secure the bowl base during use. A "Mechanical Centrifuge" uses mechanical clips to secure the bowl base, while a "Vacuum Centrifuge" uses a vacuum system to secure the bowl base. The type of centrifuge used does not affect the performance of the MCS+ device.

The mechanical centrifuge is easily distinguished from the vacuum centrifuge.

The mechanical centrifuge cover latch mechanism only requires a one-quarter turn and a downward push to unlock the cover halves. The mechanical centrifuge also features six mechanical clips on the centrifuge chuck which secure the bowl base as the bowl is snapped into place.

The vacuum centrifuge cover latch mechanism requires several turns before the cover halves can be separated. The vacuum centrifuge also has an "L" shaped gasket on the centrifuge chuck to assist the vacuum system in securing the bowl base into place.

Warning! The silicone grease used in vacuum centrifuges should never be applied to a mechanical centrifuge. Do not grease any part of the mechanical centrifuge. If grease has been applied to the mechanical chuck, contact Haemonetics Field Service immediately.

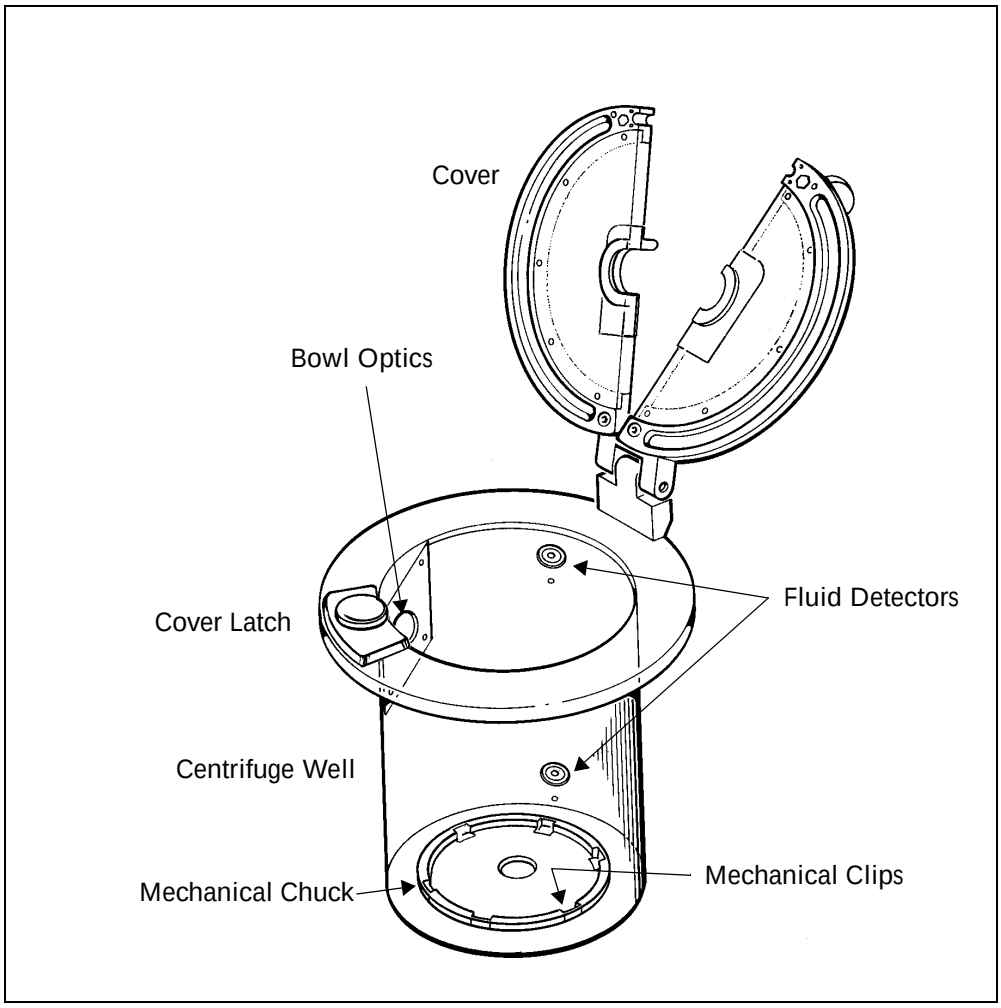

Figure 6-1 , Mechanical Centrifuge

Warning! In order to function properly, the Bowl Optics must be clean and clear. A dirty or clouded lens on the Bowl Optics could interfere with its proper function.

Warning! If the cleaning solution should come in contact with the Bowl Optics, the operator should rinse the lens with clear water and dry it so that the lens is not clouded.

Mechanical Centrifuge Well and Cover

The Centrifuge Well and Cover should be cleaned monthly as well as any time a spill occurs. The following cleaning methods are recommended to ensure proper cleaning and to eliminate harm to machine components.

✍ *Note: Two biohazard waste bags are included with each MCS+* device*. The bags are located under the machine on a tray. One of the bags is connected to the Centrifuge Drain Tube, and a second is provided to replace the connected bag. Replacement bags may be ordered through Customer Service. Call the Haemonetics Technical Hot Line at (800) 537-2802 in case of any machine or bowl malfunction.*

For routine cleaning:

1. During machine operation and Centrifuge maintenance, ensure that a waste bag is attached to the Centrifuge Drain Tube (a plastic tube exiting the base of the machine) and that it hangs freely at the back of the machine.

Warning! If the cleaning solution should come in contact with the Bowl Optics, the operator should rinse the lens with clear water and dry it so that the lens is not clouded.

2. Wash the Centrifuge Cover with a cloth moistened with cleaning solution.

To clean a fluid spill:

1. Power off the machine and disconnect the power cord from the outlet. Ensure that the waste bag is attached to the Centrifuge Drain Tube (a plastic tube exiting the base of the machine) and that it hangs freely at the back of the machine.
2. Wipe away as much fluid/blood as possible with gauze pads. Spray cleaning solution followed by a clear water rinse against the wall of the Centrifuge avoiding the Centrifuge Chuck, the Bowl Optics, and the Fluid Sensors. Allow the fluid to flow into the waste bag attached to the drain at the base of the machine. Be sure to confirm that the fluid is flowing into the waste bag.

Warning! If the cleaning solution should come in contact with the Bowl Optics, the operator should rinse the lens with clear water and dry it so that the lens is not clouded.

3. Wash the Centrifuge Cover with a cloth moistened with cleaning solution.
4. Close the slide clamp of the used waste bag. Remove the bag and discard it according to the facility's SOP for disposition of biohazardous wastes. Replace the bag with the spare and call Haemonetics to report the spill and request another waste bag.
5. Inspect the mechanical fingers and ensure that they move freely.

Vacuum Centrifuge Well and Cover

Warning! In order to function properly, the Bowl Optics must be clean and clear. A dirty or clouded lens on the Bowl Optics could interfere with its proper function.

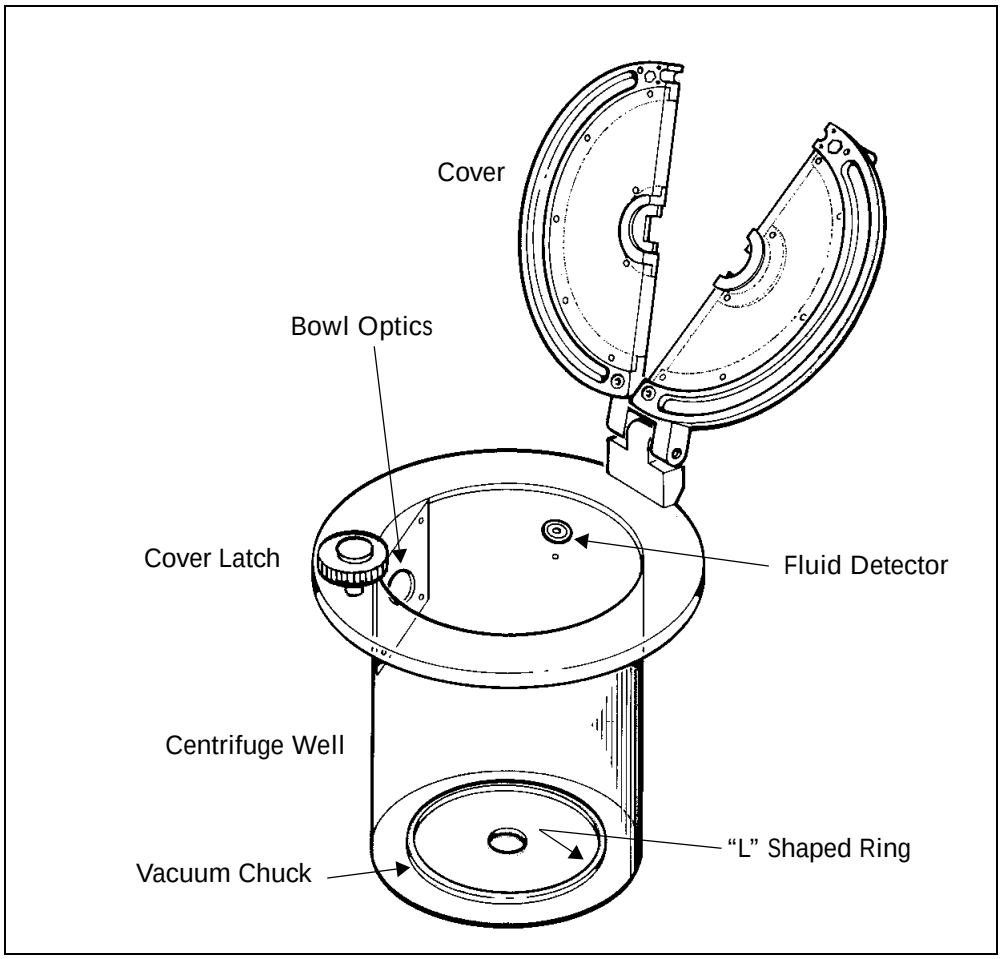

Figure 6-2, Vacuum Centrifuge

Warning! If the cleaning solution should come in contact with the Bowl Optics, the operator should rinse the lens with clear water and dry it so that the lens is not clouded.

The Vacuum Centrifuge Well and Cover should be cleaned monthly as well as any time a spill occurs. The following cleaning methods are recommended to ensure proper cleaning and to eliminate harm to machine components.

Note: Two biohazard waste bags are included with each MCS+ device*. The bags are located under the machine on a tray. One of the bags is connected to the Centrifuge Drain Tube, and a second is provided to replace the connected bag. Replacement bags may be ordered through Customer Service. Call the Haemonetics Technical Hot Line at (800) 537-2802 in case of any machine or bowl malfunction.*

For routine cleaning:

1. During machine operation and Centrifuge maintenance, ensure that a waste bag is attached to the Centrifuge Drain Tube (a plastic tube exiting the base of the machine) and that it hangs freely at the back of the machine.
2. Cover the hole in the center of the Centrifuge Chuck with tape to protect the internal vacuum system from fluid damage. Wipe the walls of the Centrifuge with a damp cloth, avoiding the Bowl Optics and Fluid Sensor.

Warning! If the cleaning solution should come in contact with the Bowl Optics, the operator should rinse the lens with clear water and dry it so that the lens is not clouded.

Warning! Do not allow cleaning solutions to enter the Vacuum Chuck (in the center of the Centrifuge).

3. Wash the Centrifuge Cover with a cloth moistened with cleaning solution.
4. Remove the tape from the Centrifuge Chuck and dry all surfaces.
5. An “L” Shaped Ring is located in the Centrifuge (refer to Figure 6-1) Chuck. To grease the ring, reach into the lowest part of the Centrifuge and rub a small amount of silicone grease onto the ring with a finger ensuring an even amount around the ring.

To clean a fluid spill:

1. Power off the machine and disconnect the power cord from the outlet. Ensure that the waste bag is attached to the Centrifuge Drain Tube (a plastic tube exiting the base of the machine) and that it hangs freely at the back of the machine.
2. Cover the hole in the center of the Centrifuge Chuck with tape to protect the internal vacuum system from fluid damage. Wipe away as much blood as possible with gauze pads. Spray cleaning solution followed by a clear water rinse against the wall of the Centrifuge, avoiding the Centrifuge Chuck, the Bowl Optics, and the Fluid Sensor. Allow the fluid to flow into the waste bag attached to the drain at the base of the machine. Be sure to confirm that fluid is flowing into the waste bag.

Warning! If the cleaning solution should come in contact with the Bowl Optics, the operator should rinse the lens with clear water and dry it so that the lens is not clouded.

Warning! Do not allow cleaning solutions to enter the Vacuum Chuck (in the center of the Centrifuge).

3. Wash the Centrifuge Cover with a cloth moistened with cleaning solution.
4. Remove the tape from the Centrifuge Chuck and dry all surfaces.

5. Close the slide clamp of the used waste bag. Remove the bag and discard it according to the facility's SOP for disposition of biohazardous wastes. Replace the bag with the spare and call Haemonetics to report the spill and request another waste bag.

Cleaning the Optics Lens

Bowl Optics

The Bowl Optics should be cleaned monthly.

1. Wipe the Bowl Optics with a lint-free cloth moistened with water.
2. Dry the Bowl Optics with another lint-free cloth.

The window of the Bowl Optics located inside the Centrifuge may be cleaned with a soft, damp, lint-free cloth (moistened with water only). The optic lens should be cleaned monthly or when a spill occurs.

Warning! In order to function properly, the optical sensor lens must be clean and clear. A dirty or clouded lens could interfere with proper operation of the sensor. Always clean the optical lens after a blood spill.

Cleaning the Line Sensor

Line Sensor

The line sensor should be cleaned at least once each month as well as any time a spill has occurred.

1. Gently wash the groove of the line sensor with a lint-free cloth moistened with clear, warm water.
2. Dry the groove with a lint-free cloth.

Warning! The line sensor must be clean to function properly. If it is not clean, it may interfere with the proper performance of the apheresis procedure.

Cleaning the Disposable Identification Window

Disposable Identification Window

The disposable identification window is located next to the blood and white pump manifold. The disposable identification window should be cleaned monthly.

1. Wipe the disposable identification window with a lint-free cloth moistened with water.
2. Dry the disposable identification window with another lint-free cloth.

Cleaning the Blood, White, and Anticoagulant Pumps

The pumps should be cleaned monthly or more frequently if needed. Always clean the pumps after a fluid spill. A build-up of tubing debris or fluids may interfere with pump efficiency. The following cleaning method is recommended.

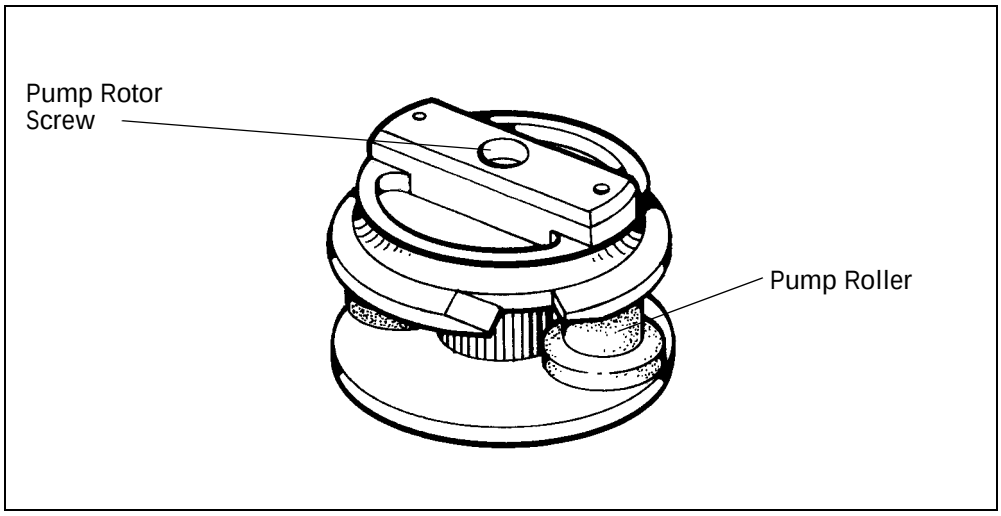

Figure 6-3, Pump Rotor Assembly

1. Loosen the Pump Rotor screw located in the center of the Pump Roller Assembly.
2. Lift the round Pump Rotor section out of the Pump Assembly.
3. Wash the entire Roller Assembly with cleaning solution and rub away any debris on the Roller Assembly. Ensure that all the rollers turn freely on the Roller Assembly.
4. Rinse with clear water to rinse away the cleaning solution.
5. Dry the assembly with a lint-free towel.
6. Replace the Roller Assembly into the Pump Well. It may be necessary to remove debris from the pumps between cleanings. A small brush has been provided in the tool kit for this purpose.

Cleaning the Control Panel

The exterior of the MCS+ device should be cleaned with a mild detergent or disinfectant at regular intervals as well as any time a spill occurs. Do not use 100% bleach directly on the machine; a 10% bleach/water solution or other disinfectant may be used.

Cleaning the Air Detectors

The Air Detectors should be cleaned monthly.

1. Gently wash the grooves of the Anticoagulant Line Air Detector, Donor Line Air Detectors, and Blood Line Air Detector monthly with a lint-free cloth moistened with clear, warm water.
2. Dry the grooves.

Cleaning the Air Filter

The MCS+ device is equipped with air filters for incoming cooling air on the bottom of the MCS+ device. Correct filter maintenance will avoid malfunction resulting from an accumulation of lint and dust in air passages. The filter should be washed quarterly, depending upon frequency and conditions of use.

Supplies Needed

The only supply needed is warm running water.

Filter Cleaning Procedure

Cleaning the air filter is simple and easy. The following steps outline the correct procedure.

Note: There are two types of machine stands requiring two methods of filter access for cleaning. Stand A is a black metal stand with one center support post. This stand will require removal of the machine for filter access. Stand B has filter access holes in the top shelf and is also distinguishable by a middle basket and bottom shelf for supply storage. You will not be required to remove the machine from the stand with this style.

Stand A:

1. Unplug the MCS+ device.
2. Tip the machine onto its side.
3. Grasp the filters and pull them out.
4. Rinse each filter under warm running water until it is clean. **Do not use soap or any cleaning solution.**
5. Squeeze out excess water, place on a clean cloth, and let dry overnight.

Warning! To avoid electrical shock, do not place a wet filter into the machine.

6. Install the filters through the access holes and ensure they are properly seated into the filter groove.

Stand B:

1. Unplug the MCS+ device.
2. Reach through the access holes on the top shelf and grasp the filters from the bottom of the machine.
3. Rinse each filter under warm running water until it is clean. **Do not use soap or any cleaning solution.**
4. Squeeze out excess water, place on a clean cloth, and let dry overnight.

Warning! To avoid electrical shock, do not place a wet filter into the machine.

5. Install the filters through the access holes and ensure they are properly seated into the filter groove.

Cleaning the Exterior Surfaces and User Panel

The exterior surfaces and user panel should be cleaned monthly.

1. Wipe the exterior surfaces and user panel with a lint-free cloth moistened with water.
2. Dry with a lint-free cloth.

Cleaning the DPM and SPM

The DPM and SPM should be cleaned daily.

1. Push white circular sleeve of the DPM with thumb as far in as possible to expose tapered aluminum luer filter adapter.
2. While pushing onto sleeve, use your other hand to wipe the exposed area of the luer filter adapter with the alcohol pad using a circular motion (reaching as far in as possible) to remove any residue.
3. Dry luer filter adapter with a gauze pad. (Wipe in a circular manner.)
4. Inspect luer filter adapter closely to make sure no residue remains.
5. If necessary, repeat step 2 to step 4 to remove stubborn layer(s) of residue that is (are) still visible after initial cleaning.
6. Repeat steps 1 through 5 for the System Pressure Monitor.

Leakage Current

Haemonetics recommends that leakage current be checked as local regulations dictate, to assure the machine continues to qualify under this standard. As a precaution, leakage current should be checked in the event of a blood spill or major voltage surge in the house electrical system.

Warning! Leakage current is a primary indication of electrical shock hazard. Each MCS+ device is carefully checked during final factory inspection to verify that leakage current is less than less than 100 microamperes at 110 VAC and less than 500 microamperes at 220 VAC.

FIELD SERVICE

Throughout the United States and in many locations worldwide, Haemonetics maintains a network of factory-trained field service engineers. If a problem should arise, a blood processing equipment specialist can usually be on-site within twenty-four hours to evaluate and correct any malfunction. Your field service engineer can also answer any questions about routine maintenance and quality control. Maintenance contracts are available to ensure that your Haemonetics instrument continues to function well. In the continental U.S., Field Service may be reached by calling (800) 537-2802.

CLINICAL SERVICES

Installation and Training

Haemonetics Clinical Specialists proficient in the technical aspects of all Haemonetics equipment are available to train personnel in the use of the MCS+ device. Upon delivery of the MCS+ device, training of the apheresis staff will be scheduled by your Haemonetics representative. To schedule a Clinical In-Service please contact your local sales representative.

Hot Line

Services available for handling emergency telephone calls will depend upon the country in which the MCS+ device operator is located. In North America, Haemonetics has a twenty-four hour, toll-free hot line. A specialist is always available to answer questions regarding the operation and use of Haemonetics equipment. The Clinical Hot Line number is (800) 433-3431. The Technical Hot Line number is (800) 537-2802. Outside North America, the apheresis operator should contact his or her local Haemonetics representative to determine the appropriate channel of communication.

RETURNED GOODS AUTHORIZATION (RGA) SYSTEM

The Returned Goods Authorization (RGA) System outlines the procedures to be followed when returning goods. The system ensures that returned goods are properly handled and analyzed. Because of the potential health hazard inherent in the shipment, handling, and defect analysis of biologically contaminated products, it is important that these procedures be carefully followed.

RGA Procedure

The steps that should be followed in returning any equipment or disposable are outlined below. All disposables to be picked up by courier for return to Haemonetics should be handled according to the coordinator's instructions. Merchandise shipped in error by Haemonetics will be handled by the Customer Services Department, at (800) 225-5297.

1. Call the Product Complaint Coordinator at (800) 225-5242, x9622, to return any product you feel is unacceptable for patient, donor, or blood bank use.
2. The coordinator will request the following information:
   a. Product list number.
   b. Product lot number and outdate.
   c. The quantity to be returned.
   d. The defect noted.
   e. The number of cartons being returned.
3. The coordinator will inform you of the additional steps that need to be taken at this point.
4. If the disposables have been exposed to blood, you must provide a detailed description of the problem you experienced. You must also supply the same information as detailed earlier (i.e., product list number, lot number, etc.). In many situations, you will be asked to dispose of these goods after reporting the defect.
5. Should Haemonetics request the return of contaminated disposables or equipment, the disposables or equipment must be decontaminated prior to shipment pursuant to those policies and procedures dictated by the medical facility's Exposure Control Plan, as required by OSHA Bloodborne Pathogen Standard. Repackaging of equipment or disposables for return to Haemonetics must comply with U.S. Department of Transportation regulations for interstate shipment of blood-contaminated products.

Warning! Materials returned unwashed cannot be analyzed and pose a potentially serious health hazard to individuals involved in shipping, handling, and testing.

Table 6-1, Maintenance Schedule

Clean centrifuge cover and well	Monthly and with a spill
Inspect L gasket and apply silicone grease (Vacuum centrifuge only)	Monthly
Clean bowl optics lens	Monthly and with a spill
Clean disposable ID window	Monthly
Clean pumps	Monthly and with a spill
Clean exterior surfaces and user panel	Monthly and with a spill
Clean air detectors	Monthly
Clean line sensor	Monthly
Clean air filters	Quarterly
Clean DPM and SPM	Daily
Check current leakage	Per local regulations and with a blood spill or major voltage surge
Preventive maintenance	Annually

Monthly Cleaning and Maintenance record — MCS®+ Device

Year _____

Machine Serial number _____

Action	*Jan*	*Feb*	*Mar*	*Apr*	*May*	*Jun*	*Jul*	*Aug*	*Sept*	*Oct*	*Nov*	*Dec*
Clean centrifuge cover and well												
Inspect “L” gasket and apply silicone grease (Vacuum Centrifuge only)												
Clean bowl optics lens												
Clean disposable identification window												
Clean pumps												
Clean exterior and user panel												
Clean air detectors/line sensor												
Clean air filters												
Check current leakage												
Maintenance performed by (date and initials)												
Reviewed by (date and initials)												

Annual preventive maintenance (Scheduled by supervisor as appropriate and performed by Haemonetics service representative or a qualified biomedical engineer). See manual for recommended maintenance schedule. Haemonetics Technical Support is available at (800) 537-2802 to assist in determining the appropriate maintenance schedule.

Name of person performing preventive maintenance: _____ Date of preventive maintenance _____

Reviewed by: _____ (Date/Initial)

Chapter Seven

REFERENCE INFORMATION

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- AC Volume Returned to the Donor or Patient. 7-3
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REFERENCE CALCULATIONS

Anticoagulant in Product

The concentration of anticoagulant in a platelet or plasma product is a function of the Anticoagulation Ratio ("AC Ratio") and Donor Hematocrit. Table 7-1 gives the concentration of anticoagulant in the collected plasma or platelet product.

To determine the total volume of anticoagulant in a plasma or platelet product use the following procedure:

- Determine the concentration of anticoagulant in the product from Table 7-1.
- The total volume of anticoagulant in collected products can be calculated by multiplying the concentration of anticoagulant in the plasma by the volume of the product:

$$\text{AC Volume in Product} = \frac{\text{\% AC in Product}}{100} \times \text{Product Volume}$$

Table 7-1: Concentration of anticoagulant in plasma or platelet products

AC Ratio	*1:8*	*1:9*	*1:10*	*1:11*	*1:12*	*1:16*
Donor Hematocrit	**% Anticoagulant in the plasma or platelet product**					
20	15.2%	13.5%	12.2%	11.1%	10.2%	7.7%
22	15.5%	13.8%	12.5%	11.4%	10.4%	7.9%
24	15.8%	14.1%	12.8%	11.6%	10.7%	8.1%
26	16.2%	14.5%	13.1%	11.9%	10.9%	8.3%
28	16.6%	14.8%	13.4%	12.2%	11.2%	8.5%
30	16.9%	15.2%	13.7%	12.5%	11.5%	8.7%
32	17.4%	15.5%	14.0%	12.8%	11.8%	8.9%
34	17.8%	15.9%	14.4%	13.2%	12.1%	9.2%
36	18.2%	16.3%	14.8%	13.5%	12.4%	9.4%
37	18.5%	16.6%	15.0%	13.7%	12.6%	9.6%
38	18.7%	16.8%	15.2%	13.9%	12.8%	9.7%
39	19.0%	17.0%	15.4%	14.1%	13.0%	9.9%
40	19.2%	17.2%	15.6%	14.3%	13.2%	10.0%
41	19.5%	17.5%	15.8%	14.5%	13.4%	10.2%

Table 7-1: Concentration of anticoagulant in plasma or platelet products

AC Ratio	***1:8***	***1:9***	***1:10***	***1:11***	***1:12***	***1:16***
Donor Hematocrit	**% Anticoagulant in the plasma or platelet product**					
42	19.8%	17.7%	16.1%	14.7%	13.6%	10.3%
43	20.0%	18.0%	16.3%	14.9%	13.8%	10.5%
44	20.3%	18.2%	16.6%	15.2%	14.0%	10.6%
45	20.6%	18.5%	16.8%	15.4%	14.2%	10.8%
46	20.9%	18.8%	17.1%	15.6%	14.4%	11.0%
47	21.2%	19.1%	17.3%	15.9%	14.6%	11.2%
48	21.6%	19.4%	17.6%	16.1%	14.9%	11.4%
49	21.9%	19.7%	17.9%	16.4%	15.1%	11.6%
50	22.2%	20.0%	18.2%	16.7%	15.4%	11.8%
60	26.3%	23.8%	21.7%	20.0%	18.5%	14.3%

AC Volume Returned to the Donor or Patient

The volume of anticoagulant infused is calculated as follows:

1. Determine the total volume of anticoagulant in the plasma and platelet bags using Table 7-1 above.
2. Read the volume of anticoagulant used (“AC Used”) from the HaemoUpdate or Procedure Complete Screen.
3. The volume of anticoagulant infused equals AC used – AC in product.

Total Blood Volume Calculations

The MCS+ device displays the estimated total blood volume of the donor on screen. The method used by the MCS+ device is the Nädler equation as given by the AABB *Technical Manual* (12th edition, page 741). Charts 7-1 and 7-2 depict the estimated blood volume.

To estimate the total blood volume of a donor:

1. Select the correct chart (for males or females).
2. Select the height of the donor or patient on the Y (Height) axis.
3. Select the weight of the donor in pounds on the top X (Weight) axis.
4. Find the point in the chart where the Height and Weight intersect.
5. Follow the curved blood volume line down to the correct reading for estimated blood volume.

Example: A 5'8" male who weighs 180 lb. has an estimated blood volume of 5400 ml.

The equations used by the MCS+ device are:

For males

$$\text{Estimated Blood Volume} = 2740 \times \sqrt{\frac{\text{Height (in)} \times \text{Weight (lb)}}{3131}}$$

or…

$$\text{Estimated Blood Volume} = 2740 \times \sqrt{\frac{\text{Height (cm)} \times \text{Weight (Kg)}}{3600}}$$

For females

$$\text{Estimated Blood Volume} = 2370 \times \sqrt{\frac{\text{Height (in)} \times \text{Weight (lb)}}{3131}}$$

or…

$$\text{Estimated Blood Volume} = 2370 \times \sqrt{\frac{\text{Height (cm)} \times \text{Weight (Kg)}}{3600}}$$

Chart 7-1: Estimated Blood Volume for Males Utilizing Nädler Equation

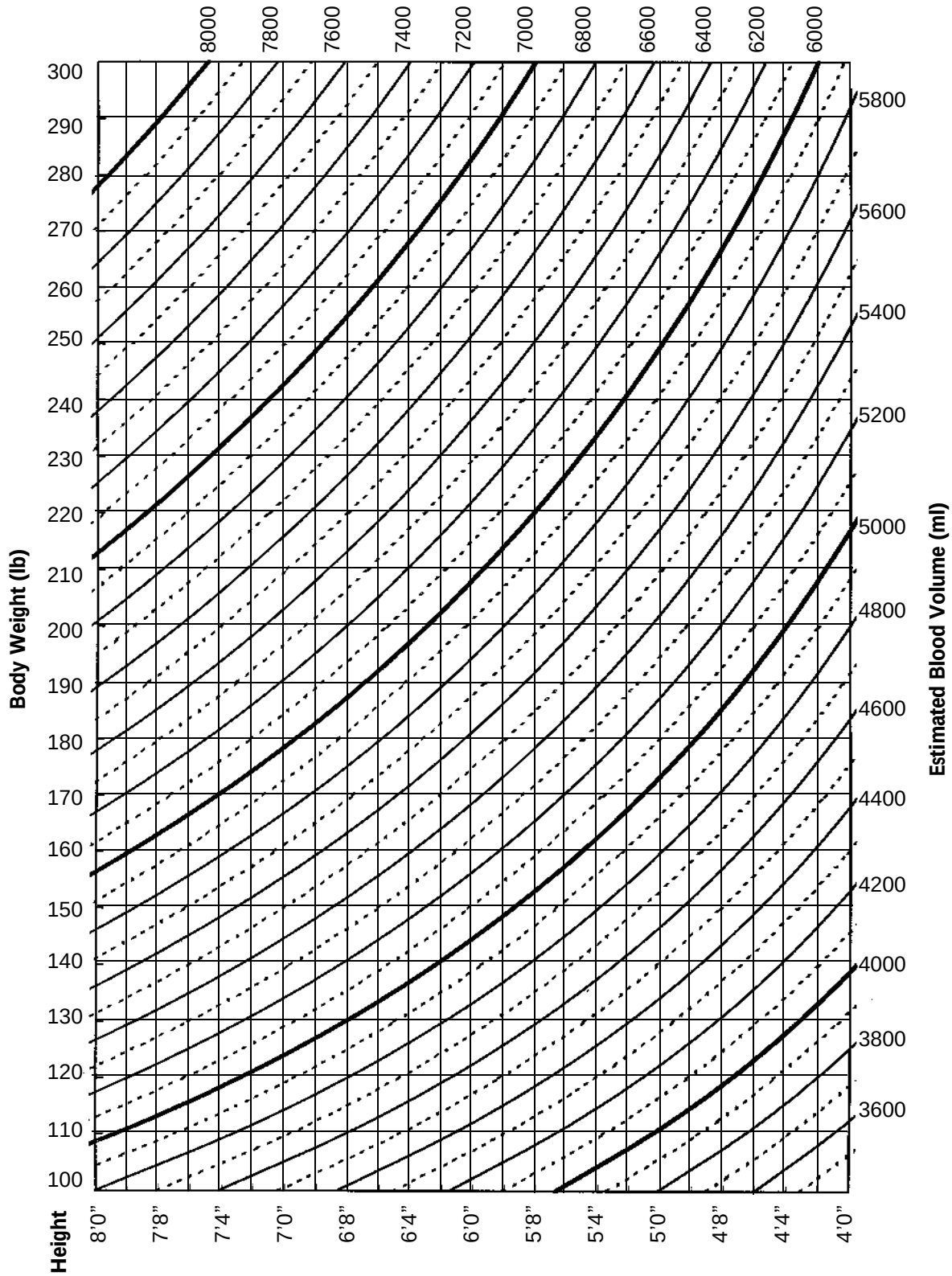
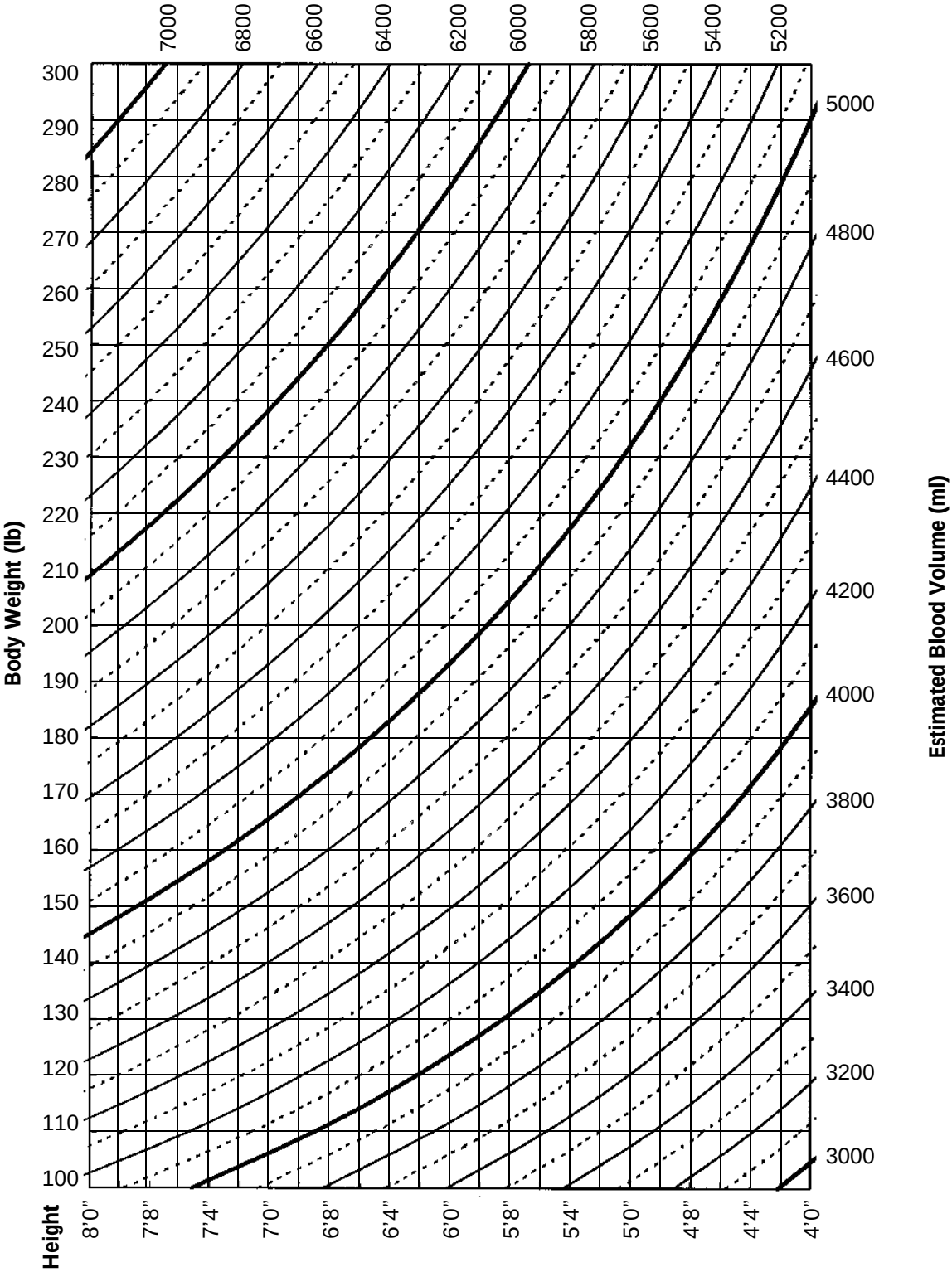


Chart 7-2: Estimated Blood Volume for Females Utilizing Nädler Equation



Expected Extracorporeal Volume

The maximum Extracorporeal Volume (ECV) per cycle can be estimated by subtracting the volume of anticoagulant used from the volume processed and dividing by the cycle number. The most accurate estimation is obtained during the first return mode.

Table 7-2 gives the expected maximum extracorporeal blood volume and extracorporeal red cell volume as a function of the donor's hematocrit for platelet procedures. The maximum EC red blood cells is the total volume of red cells expected to be in the disposable at the start of the return mode. The maximum volume of red cells in the LN 994 disposable does not exceed 190 ml.

✍ *Note: These volumes do not include any blood samples taken prior to the procedure.*

✍ *Note: Individual charts for expected extracorporeal volume for protocols other than platelets are given in the individual protocol manuals.*

Table 7-2: Expected Maximum ECV and EC Red Blood Cells for Platelet Procedures

Donor Hematocrit	*Maximum ECV*	*Maximum EC Red Blood Cells*
38	480	182
39	471	184
40	463	185
41	454	186
42	445	187
43	437	188
44	428	188
45	419	189
46	411	189
47	402	189
48	393	189
49	385	188
50	376	188
51	367	187
52	359	187

To determine the expected maximum % ECV out, divide the expected maximum ECV by the estimated total blood volume of the donor.

$$\text{Expected \% ECV} = 100 \times \frac{\text{Expected Maximum ECV}}{\text{Estimated Blood Volume}}$$

For a platelet procedure a 5'0", 110 lb. female (estimated blood volume is 3500 ml) with a hematocrit of 38% is expected to have a maximum ECV of 480 ml, and a % ECV of 100 x 480/3500 = 13.7%.

✍ *Note: Only donors with a hematocrit less than 38% AND a blood volume of less than 3200 ml are expected to reach an ECV of more than 15%.*

Determining Product Volume

The MCS+ device determines product volumes either by pump revolutions, or by product weight. In the SDP and PLP protocols, the plasma and platelet product volumes are determined by the weigher of the MCS+ device. To convert the product weight to a volume, the MCS+ device applies a conversion factor of 1.026 g/ml. The Procedure Complete Screen and HaemoUpdate Screen give detailed product volume information.

To manually determine the collected product volume, weigh the total product on a calibrated scale, and subtract the weight of the empty bags from the product weight and divide by 1.026 g/ml.

$$\text{Product Volume} = \frac{\text{Total Weight} - \text{Empty Bag Weight}}{1.026} \text{ ml}$$

Calculating Platelet Yields

The platelet yield in a platelet product is calculated by multiplying the concentration of platelets in the product by the total product volume. The platelet yield is calculated in 10^{11} platelets.

$$\text{Platelet Yield} = \frac{\text{Platelet Concentration} \times \text{Product Volume}}{100{,}000} \; 10^{11} \text{ Platelets}$$

Where the platelet concentration is in 10^3/µl or 10^6/ml, the factor 100,000 is used to arrive at the correct number of digits. For example, if the platelet concentration in the product is 1300 x 10^3 µl and the product volume was 300 ml, the yield would have been 1300 x 300 / 100,000 is 3.9 x 10^{11} platelets.

Calculating Platelet Efficiencies

The platelet collection efficiency can be calculated by dividing the platelet yield by the total number of platelets that have been processed. The preferred method of calculating the Platelet Collection Efficiency is based on the average of donor pre- and donor post-platelet counts. When a post-platelet count is not available, the donor precount will suffice.

To calculate the platelet collection efficiency:

1. Determine the average platelet count of the donor:
   - If both a platelet pre-count and a post-count are available, use the average of the pre- and post-counts.
   - If only a pre-count is available, use the pre-count.
2. Determine the net volume of donor blood processed by subtracting the volume of anticoagulant used from the total volume processed during the procedure.

   Donor Blood Processed = Total Volume Processed – AC Volume Processed

3. Next, calculate the number of platelets that passed through the bowl during the procedure:

$$\text{Platelets Processed} = \frac{\text{Platelet Count x Donor Blood Processed}}{100{,}000} \text{ Platelets}$$

Example: If the donor platelet count was 250 10^3/µl and the total donor blood processed was 3500 ml, the total number of platelets processed was 250 x 3500 / 100,000 = 8.75 10^{11} platelets processed through the bowl.

4. And the platelet collection efficiency is:

$$\text{Platelet Efficiency} = \frac{\text{Actual Platelet Yield}}{\text{Platelets Processed}} \text{ x } 100\%$$

ANTICOAGULANTS

ACD-A

ACD-A is the most commonly used anticoagulant. The anticoagulant ratio used depends on which component is being collected. The anticoagulant ratio is typically between 1:8 and 1:12. Refer to the appropriate protocol manual for optimal anticoagulant ratios.

ACD-B

ACD-B is occasionally used in therapeutic apheresis. The anticoagulant ratio used depends on the type of procedure performed. The anticoagulant ratio used for ACD-B is typically between 1:8 and 1:12. Refer to the appropriate protocol manual for optimal anticoagulant ratios.

Sodium Citrate

Sodium Citrate may be substituted for ACD-A or ACD-B in therapeutic apheresis procedures. The most frequently used concentration of citrate is 4% citrate at a 1:16 anticoagulant ratio.

To make a known citrate concentration (% Citrate), mix 46.7% (14g citrate/30ml) Trisodium Citrate with the Saline, ACD-A or ACD-B. The volume of 46.7% citrate required for each of the solutions is given in Table 7-3.

Table 7-3:
Milliliters of 46.7% Sodium Citrate required for given concentrations of Citrate

% Citrate Required	*500 ml ACD-A (3%)*	*500 ml ACD-B (2%)*	*500 ml Normal Saline*	*250 ml Normal Saline*
2	—	—	21.6	10.8
3	—	10.8	32.0	16.0
4	10.8	21.6	42.8	21.5
5	32.0	42.8	64	32.0

Heparin

Heparin may be substituted for citrate anticoagulants during therapeutic plasma exchange. The dosages most frequently used are:

- 35,000 units / 500 ml 0.9% Normal Saline if using a 1:16 anticoagulant ratio.
- 17,500 units / 500 ml 0.9% Normal Saline if using a 1:8 anticoagulant ratio.

✍ *Note: Physician discretion determines anticoagulant used as well as whether heparin may be substituted.*